DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Rockville MD 20857

Ms. Pamela L. Misajon
Regulatory Affairs and Quality Assurance Manager
CardioVascular Dynamics, Inc.
13700 Alton Parkway
Irvine, California 92618

FEB 20 1998

Re: P970052
FACT™, ARC™, LYNX™ and Guardian™
Balloon Coronary Dilatation Catheters
Filed: November 4, 1997
Amended: November 12 and 26, 1997

Dear Ms. Misajon:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the FACT™, ARC™, LYNX™ and Guardian™ Balloon Coronary Dilatation Catheters. These devices are indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The application includes authorization from Endosonics Corporation, Rancho Cordova, CA, to incorporate information contained in its approved premarket approval application and related supplements for the Cathscanner® Oracle® Micro PTCA Catheter. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Expiration dating for these devices has been established and approved at two years.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the

notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Brad C. Astor at (301) 443-8243.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Issued: 5-2-95

CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant**(s)** involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 240
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)
Center for Devices and Radiological Health
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Summary of Safety and Effectiveness Data

I. General Information

A. Device Generic Name: percutaneous transluminal coronary angioplasty (PTCA) balloon catheters

B. Device Trade Name: FACT™, ARC™, LYNX™ and Guardian™ Balloon Coronary Dilatation Catheters

C. Applicant's Name and Address: CardioVascular Dynamics, Incorporated
13700 Alton Parkway
Irvine, California 92618

D. Premarket Approval Application (PMA) Number: P970052

E. Date of Panel Recommendation: April 12, 1993 (P910031)

FEB 20 1998

F. Date of Notice of Approval to Applicant:

II. Indications

The FACT™, ARC™, LYNX™ and Guardian™ Balloon Coronary Dilatation Catheters are indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

III. Center for Devices and Radiological Health (CDRH) Decision

The application includes by reference the data in PMA P910031 and related supplements for the Cathscanner® Oracle® Micro PTCA Catheter submitted by Endosonics Corporation and approved by FDA on September 30, 1994. Endosonics Corporation has authorized CardioVascular Dynamics to incorporate by reference the information contained in its approved PMA and related supplements.

The FACT™, ARC™, LYNX™ and Guardian™ Balloon Coronary Dilatation Catheters are modified versions of the Cathscanner® Oracle® Micro PTCA Catheter. These devices do not incorporate the ultrasound transducer found on the Cathscanner® Oracle® Micro PTCA Catheter and are therefore not indicated for intravascular imaging. The dilatation balloons of these devices range from 18 to 30 mm in length and from 2.0 to 4.0 mm in diameter. The FACT™, ARC™, LYNX™ and Guardian™ Balloon Coronary Dilatation Catheters were approved through supplements to PMA P910031 on the following dates, respectively: October 3, 1995, March 3, 1996, April 9 and November 11, 1997.

CDRH approval of the CardioVascular Dynamics, Incorporated PMA is based on (1) the safety and effectiveness data contained in P910031 and related supplements and (2) the results of the FDA inspection of the manufacturing facilities. A summary of safety and effectiveness data for the Cathscanner® Oracle® Micro PTCA Catheter appears in Attachment A. The indications for use of the devices covered under this approval differ from those in the summary of safety and effectiveness for the Cathscanner® Oracle® Micro PTCA Catheter due to the implementation of a PTCA package insert template, to be used by all PTCA catheter manufacturers, after approval of the Cathscanner® Oracle® Micro PTCA Catheter. Manufacturers of PTCA catheters were informed of the necessary changes to their existing labels in a letter dated February 7, 1995. These changes to PTCA catheter labeling were made to ensure consistency among device manufacturers and to reflect current practice in the medical community.

On April 12, 1993, the Circulatory System Devices Advisory Panel reviewed the PMA for the Cathscanner® Oracle® Micro PTCA Catheter (P910031) and recommended that the application be found Not Approvable, based on the lack of clinical data for the Oracle® Micro PTCA Catheter at that time. The application included data from 86 patients treated with the subject device, and the panel requested that the results of 200 subjects treated with the Oracle® Micro PTCA Catheter, with clinical follow-up to two months, be submitted to demonstrate the safety of the catheter. FDA concurred with the recommendations of the panel. A Not Approvable letter to that effect was issued to the applicant on September 24, 1993. On December 27, 1993, and September 6, 1994, the applicant submitted amendments to the application providing the information required by FDA. The amendments were reviewed by FDA and found to sufficiently demonstrate the safety and effectiveness of the device. FDA approved this application (P910031) and final labeling on September 30, 1994. In accordance with CDRH'' announced policy (4/18/86 PMA Guidance Memorandum #86-4), this licensing PMA was not taken to the Panel.

IV. Approval Specifications

The standard "Conditions of Approval" enclosed with the approval order apply to the subject devices.

Directions for Use: See the labeling

Hazards to Health from Use of the Device: See Indications, Contraindications, Warnings, Precautions and Adverse Effects in the labeling.

The Approval Order, Summary of Safety and Effectiveness Data, and labeling can be found on the web site at address "http://www.fda.gov/cdrh/pmapage,html."

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Summary of Safety and Effectiveness

I. General Information

Device Generic Name:	Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter
Device Trade Name:	Endosonics Oracle™ Micro PTCA Catheter Models 55120, 55125, 55130 and 55135
Applicant:	Endosonics Corporation 3078-B Prospect Park Drive Rancho Cordova, California 95670
PMA Number:	P910031
Date of Notice of Approval to Applicant:	SEP 30 1994

II. Indications

PTCA is indicated for in patients with coronary artery disease who are acceptable candidates for coronary artery bypass graft surgery, and who meet one of the following selection criteria:

1. Single vessel atherosclerotic coronary artery disease that is discrete and accessible to a dilatation catheter.

2. Multiple vessel coronary artery disease under certain circumstances.

3. Coronary artery disease of the native coronary arteries and/or coronary artery bypass grafts of some patients who have previously undergone coronary artery bypass graft surgery, who have recurrence of symptoms, and (a) progression of disease, or (b) stenosis and closure of the grafts.

The Endosonics Oracle™ Micro PTCA Catheter is further indicated for use following balloon dilatation as an adjunct to conventional angiographic procedures to provide:

1. An image of the vessel lumen and wall structures.

2. Dimensional measurements from the image.

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III. Device Description

The Endosonics Oracle™ Micro PTCA Catheter is designed to be used with the Cathscanner® Intravascular Ultrasonic Imaging System, currently marketed for use with the Visions™ diagnostic imaging catheters for peripheral and coronary imaging applications. Descriptions of the Cathscanner® Intravascular Ultrasonic Imaging System and the Endosonics Oracle™ Micro PTCA Catheter are provided below:

A. Cathscanner® Intravascular Ultrasonic Imaging System

The Cathscanner® Intravascular Ultrasonic Imaging System is comprised of a catheter-mounted, solid state, ultrasonic transducer with associated electronic processing and display modules. There are four major components to the system: the Endosonics Oracle™ Micro PTCA Catheter, Patient Interface Module, Digital Processing System and User Interface.

The Endosonics Oracle™ Micro PTCA Catheter is connected to the Patient Interface Module. The Patient Interface Module is battery-powered and fully isolated. The Patient Interface Module contains control and signal conditioning circuitry as well as electrical isolation and limiting circuits. The Patient Interface Module is connected to the User Interface through fiber optic cables. There are no electrical connections between the Patient Interface Module and the User Interface.

The User Interface contains the image display and video recorder and printer and system controls. The User Interface enables the user to monitor and control various aspects of the system operation. Image gain, gray level mapping and other parameters can be varied to optimize the displayed image.

The Digital Processing System is connected to the User Interface via fiber optics. Data received from the ultrasonic transducer is processed and the resultant image is displayed on the User Interface video display.

B. Endosonics Oracle™ Micro PTCA Catheter

The Endosonics Oracle™ Micro PTCA Catheter (Oracle™ Micro Catheter) is supplied sterile and is for one time use only.

The Oracle™ Micro Catheter is available in four dilatation balloon sizes: nominally 2.0, 2.5, 3.0 and 3.5mm. An ultrasound transducer is mounted just proximal to the balloon. The catheter shaft is 3.5F, increasing to 5.0F at the transducer region. This rigid segment is 4.5mm in length. The distal tip is a coaxial design with concentric guidewire and balloon inflation lumen. The catheter shaft utilizes a three lumen tube which provides inflation, guidewire and electrical lumens. The catheter body and balloon are constructed of polyethylene. There are separate luer lock fittings at the proximal end of the catheter, one for balloon inflation and one for guidewire passage. A microcable enclosed in a single lumen tube connects the imaging transducer with the electronic imaging system. The balloon contains two radiopaque

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markers: one in the middle of the balloon and one directly under the imaging array.

The Cathscanner® Intravascular Ultrasonic Imaging System utilizes a circumferential array of solid state elements that sequentially generate and receive ultrasound signals in the Oracle™ Micro Catheter. The ultrasound array consists of multiple piezoelectric ultrasonic elements circumferentially mounted just proximal to the balloon. The transducer is 1.17 mm in diameter. The signals received are digitized and stored in high speed computer memory. Processing of these stored signals creates a cross-sectional image of the surrounding tissue. This allows 360 degree imaging without the need for moving parts.

IV. Contraindications

Candidates not acceptable for coronary artery bypass graft surgery.

Unprotected left main coronary artery disease.

Previously diagnosed episodes of coronary artery spasm.

V. Warnings/Precautions

A. Warnings

1. This device is designed and intended for one time use only. Do not resterilize and/or reuse it.

2. The dilatation catheter should only be used when the inflation device is attached. Failure to do so may result in balloon rupture due to over-pressurization.

3. Careful inspection prior to use should verify that the catheter has not been damaged in shipment and that its size (full diameter should be no larger than the diameter of the artery just distal or proximal to the stenosis), shape, and condition are suitable for the specific procedure for which it is to be used.

4. Prior to inserting the dilatation catheter into the patient, it should be tested as described in the Information for Use section. In vivo balloon pressure should never exceed the Rated Burst Pressure.

5. The short- and long-term biological effects of using an inflation pressure above that necessary to reach nominal balloon diameter are not known.

B. Precautions

1. PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be immediately performed in the event of a potentially injurious or life-threatening complication. A cardiac surgery team should be on alert while a PTCA procedure is being performed.

2. This catheter system should be used only by physicians who are experienced in coronary arteriography and who have received training in the technique of PTCA.

3. Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon when it is inside a patient.

4. During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be continued for a period of six months after the procedure.

5. When the catheters are in the body, they should only be manipulated while thay are under fluoroscopic observation with radiographic equipment that provides high-quality images.

6. The Endosonics Oracle™ Micro PTCA Catheter device is a delicate instrument and should be treated as such. Always observe the following precautions:

   a. Protect the catheter tip from impact and excessive force.

   b. Do not cut, crease, knot, or otherwise damage the catheter.

   c. Protect the electrical connections from exposure to fluid.

   d. If a guidewire is used, the outside diameter along the entire length should not exceed 0.014 inches.

   e. During use, ensure that the placement of the catheter does not preclude blood flow through the vessel.

VI. Alternative Practices and Procedures

Alternative treatment for coronary artery disease are medical therapy, coronary artery bypass graft (CABG) surgery, and non-surgical, catheter-based interventions including PTCA, atherectomy and laser angioplasty under certain circumstances.

VII. Marketing History

The Endosonics Oracle™ Micro PTCA Catheter has not been previously marketed in the United States. This device is marketed in France, Germany, Greece, Italy, the Netherlands and Switzerland. The device has not been removed from any market for reasons of safety and effectiveness.

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VIII. Potential Adverse Effects

Potential adverse effects include, but are not limited to, the following:

Dissection of the coronary artery
Injury to the coronary artery
Total occlusion of the coronary artery
Acute myocardial infarction
Unstable angina pectoris
Ventricular fibrillation
Embolization
Restenosis of the dilated artery
Coronary artery spasm
Hemorrhage or hematoma
Death

IX. Summary of Studies

A. In-Vitro (Laboratory) Studies

1. Biocompatibility and Toxicology Testing

Biological assay testing, along with the historical use in medical devices indicated that the tissue-contacting materials of the Endosonics Oracle™ Micro PTCA Catheter were biocompatible and non-toxic. The biological assays conducted include acute systemic toxicity, intracutaneous toxicity, implantation, hemolysis, and acute cytotoxicity.

2. Microbiology Testing

The Endosonics Oracle™ Micro PTCA Catheter was subjected to an ethylene oxide process to assure sterility according to the "Guideline for Industrial Ethylene Oxide Sterilization of Medical Devices" published by the Association for the Advancement of Medcial Instrumentation (AAMI). The sterility assurance level (SAL) is 10^{-6}. Results of testing validated the sterilization cycle. Samples of the Endosonics Oracle™ Micro PTCA Catheter were tested after aeration to determine if ethylene oxide or ethylene chlorohydrin or ethylene glycol were present. All residual levels were below the maximum residual limits as specified in the Federal Register 43, June 23, 1978.

3. Balloon Minimum Burst Strength Testing

The purpose of this test was to demonstrate that the minimum burst strength of the balloons are adequate for the intended use and to determine appropriate rated burst pressures. Sixty samples, at least ten of each balloon diameter, were inflated with increasing pressure until failure. The results demonstrated that with 95% confidence, 99% of the balloons will not burst at or below the rated burst pressure of 8 atm.

4. Balloon Distensibility Test

Measurements of the balloon diameter at various inflation pressures were made to determine the balloon compliance of eight balloons. The tested samples reached the nominal diameter at 5 to 8 atmospheres, and did not increase more than 8 percent past nominal at the rated burst pressure.

5. Balloon Inflation/Deflation Performance Test

To determine the maximum time to inflate and deflate the dilatation balloon, the time to inflate to 6 atm and the time to deflate was measured on a series of five catheters in a simulated coronary artery. Using a 50/50 mixture of saline and contrast solution, the time to 90% of 6 atm was less than 0.2 seconds, and the time to 99% of 6 atm was approximately 2 seconds. Deflation times to the collapsed profile using a 20 mmHg vacuum were measured at less than 4 seconds.

6. Balloon Fatigue

Cycle testing was performed to determine the ability of the balloon to withstand repeated inflations to the labeled rated burst pressure. Each balloon was attached to the pressure cycle tester and immersed in a 37° C water bath. Each balloon was subjected to forty 25 second pressurizations to the labeled rated burst pressure (8 atm) or until the balloon failed. Thirty balloons of each diameter were tested, with no failures.

7. Profile Measurements

To determine the collapsed profile of the balloon in the clinical situation, profile measurements were performed on 5 test samples of each size. After inflation to the rated burst pressure, the balloon was deflated and passed through successively smaller holes until it no longer passed. The maximum deflated profiles for the four sizes were between 0.032 and 0.038 inch.

8. Tip Pull and Bonding Test

To demonstrate the integrity of the tip of the Endosonics Oracle™ Micro PTCA Catheter, the proximal arm adapter and distal tip of five catheters were clamped. The catheter was pulled and the pull force recorded. At a minimum of 2.5 lbf, the primary failure occurred when the inner lumen detached from the multilumen shaft. This causes the electrical cable within the catheter to break, rendering the imaging portion of the device unusable. However, the catheter structure remained intact. The catheter would then stretch until a secondary failure occurred, at a minimum of 2.7 lbf.

9. Torque Strength Test

To demonstrate the torsional strength of the Endosonics Oracle™ Micro PTCA Catheter, the tip of a randomly selected catheter was held and the body rotated at the proximal connector. It was not possible to induce failure of any bonds after 80 rotations, though severe distortion of the catheter material was noted.

10. Imaging Studies

In-vitro imaging data utilizing both the Endosonics Oracle™ Micro PTCA Catheter and the Visions™ 5F Catheter with a similar 1.6 mm transducer, in conjunction with the Cathscanner® Intravascular Ultrasonic Imaging System, were collected on tissue phantoms. Studies utilizing the 1.6 mm transducer were performed on excised human arterial samples.

Utilizing both transducers, polyethylene tubes of known diameter were imaged and the ultrasound image was analyzed to determine the tube diameter. Three tubes were measured with the 1.17 mm transducer, and 8 with the 1.6 mm transducer. Multiple measurements were made in each tube. Excellent correlation was observed (r=0.99).

In-vitro imaging data utilizing the 1.6 mm transducer were collected in human tissue in 118 human arterial samples. Formalin fixed human arterial samples were placed in a saline bath, imaged, and then histologically examined. The ultrasonically determined dimensions were compared to dimensions obtained from the histological slices. Maximal lumen diameter, wall area and lumen area were compared. The correlation between ultrasonic (U) and histologic (H) measurements was determined for the various comparisons. The following correlations were noted:

Maximal Lumen Diameter N=81	U = 0.90 H + 0.08	r=0.93
Lumen Area N=80	U = 1.03 H + 0.02	r=0.97
Minimum Wall Thickness N=97	U = 0.60 H + 0.06	r=0.67
Maximum Wall Thickness N=87	U = 0.94 H + 0.11	r=0.83

The results demonstrate that the imaging system can provide adequate images of the arterial surfaces, from which dimensional measurements can be made.

11. Acoustic Output Studies

The acoustic output of the imaging transducer was measured according to the requirements of the "510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Medical Devices" of the Center for Devices and Radiological Health, Food and Drug Administration. The acoustic outputs of the transducer were found to be:

I_{spta} = 0.01189 mW/cm^2
I_{sppa} = 0.000282 W/cm^2
I_m = 0.000774 W/cm^2

12. Electrical Safety Testing

Electrical isolation testing of the Endosonics Oracle™ Micro PTCA Catheter and Cathscanner® Intravascular Ultrasonic Imaging System was conducted. The maximum leakage current was 7.6 microamps.

B. Animal Studies

The Endosonics Oracle™ Micro PTCA Catheter and Cathscanner® Intravascular Ultrasonic Imaging System were evaluated in-vivo to assess image quality, accuracy and safety of the system for use in coronary vessels. Two acute canine preparations were used. Standard 8 French large lumen guiding catheters were advanced to the coronary and cerebral vessels for selective imaging and balloon inflation observations. Data were collected continuously during scanning on videotape cassette from the imaging monitor. Simultaneous video recordings of fluoroscopic images were also collected.

Subjective data were collected on the ease of use of the Endosonics Oracle™ Micro PTCA Catheter. Trackability and torquability were adequate, as was the ability of the device to pass within the coronary vasculature and through coronary guide catheters. There was no evidence of catheter kinking or bending. No difficulties with balloon inflation or deflation occurred. Ultrasound image quality was also evaluated and found to be adequate.

In the canine coronary studies, an Endosonics Oracle™ Micro PTCA Catheter was used to dilate one artery and a marketed PTCA catheter was used to dilate another artery in each animal. The animals were sacrificed and the coronary vessels fixed under perfusion pressure. Longitudinal sections were taken in the area of balloon dilatation. Histological examination showed no evidence of unusual or unexpected damage in the vessel segments dilated by the Endosonics Oracle™ Micro PTCA Catheter as compared to the control dilatation sites.

C. Summary of Clinical Studies

A multi-center, non-randomized, prospective clinical investigation of the Endosonics Oracle™ Micro PTCA Catheter (Oracle™ Micro) was conducted to determine the safety and effectiveness of the device as used in percutaneous transluminal coronary angioplasty (PTCA), and to determine the ability of the device to provide diagnostic ultrasound information to the operator. The data were collected from 297 subjects (301 procedures*) enrolled at 21 investigational sites (29 investigators) between September 24, 1991, and December 15, 1993.

Patients considered candidates for this study were males or nonpregnant female patients with symptomatic cardiovascular disease with indication for PTCA. Patients were excluded if their renal function was abnormal or if subsequent surgery would not be feasible either for anatomic reasons or because the patients were unsatisfactory risks for general anesthesia.

1. Study Population

a. Demographic and Clinical Characteristics†

Number of Patients	297	
Mean Age (years)	60.7 ± 11.3	
range	28 - 87	
Gender (male)	211/301	70.1%
History of Smoking	174/296	58.8%
History of Diabetes	75/298	25.2%
History of Hypertension	163/298	54.7%
Family History of CAD	147/284	51.8%
Previous Infarction	140/299	46.8%
Previous CABG	32/291	11.0%
Previous PTCA	88/301	29.2%
Angina		
CHC Class 0-I	23/299	7.7%
II	58/299	19.4%
III	96/299	32.1%
IV	122/299	40.8%
Recent MI 1-3 days	21/301	6.9%
4-7 days	15/301	5.0%
Vessel Disease		
Single	163/299	54.5%
Multiple	136/299	45.5%
Ejection Fraction (%)		
Mean	56 ± 14.1	
range	16 - 90	

b. Vessel and Lesion Characteristics

Number of Vessels	358	
Number of Lesions	403	
Reference Vessel Diameter (mm)	2.91 ± 0.55	
range (mm)	1.4 - 5.0	
Minimal Lumen Diameter (mm)	0.66 ± 0.40	
range (mm)	0.0 - 2.0	
Percent Diameter Stenosis	78.7 ±13.5	
range (%)	20 - 100	
Target Vessel		
LAD	139/358	38.8%
RCA	134/358	37.4%
LCx	70/358	19.6%
Grafts	15/358	4.2%
Calcification	62/403	15.4%
Thrombus	9/403	2.2%
Eccentric	145/403	36.0%
Diffuse	60/403	14.9%

* One patient was treated in three separate procedures, and two patients were treated in two separate procedures each. These instances are presented as separate patients for purposes of demographics and acute results.

† Where the denominator differs from 301, some patients were not evaluated for the corresponding characteristic.

2. Safety Data

a. Complications

During the investigation, the following complications were noted (N=301 Procedures):

	In Hospital			Post-Discharge		
	n	%	95% C.I.†	n	%	95% C.I.†
Death	0	0.0	(0.0-1.0)	3	1.0	(0.0-2.3)
Myocardial Infarction	7	2.3	(0.9-4.7)	3	1.0	(0.0-2.3)
Q Wave	(2)	0.7	(0.1-2.4)	(2)	0.7	(0.1-2.4)
Non-Q Wave	(5)	1.7	(0.5-3.8)	(1)	0.3	(0.0-1.8)
Acute Reclosure	7	2.3	(0.9-4.7)	1	0.3	(0.0-1.8)
Emergency CABG	(3)	1.0	(0.2-2.9)	0	0.0	(0.0-1.0)
Dissection - Major‡	9	3.0	(1.4-5.6)	0	0.0	(0.0-1.0)
CABG	(1)	0.3	(0.0-1.8)	0	0.0	(0.0-1.0)
Dissection - Minor‡	14	4.7	(2.6-7.7)	0	0.0	(0.0-1.0)
Perforation	1	0.3	(0.0-1.8)	0	0.0	(0.0-1.0)
Hematoma	8	2.7	(1.2-5.2)	0	0.0	(0.0-1.0)
Surgery or Transfusion	(5)	1.7	(0.5-3.8)	0	0.0	(0.0-1.0)
Renal Failure	2	0.7	(0.1-2.4)	0	0.0	(0.0-1.0)
Congestive Heart Failure	2	0.7	(0.1-2.4)	0	0.0	(0.0-1.0)
Cerebrovascular Event	1	0.3	(0.0-1.8)	0	0.0	(0.0-1.0)
Femoral Pseudoaneurysm Surgical Repair	1	0.3	(0.0-1.8)	0	0.0	(0.0-1.0)
Peripheral Vascular Occlusion	1	0.3	(0.0-1.8)	0	0.0	(0.0-1.0)
Ventricular Fibrillation	6	2.0	(0.7-4.3)	0	0.0	(0.0-1.0)
Atrial Fibrillation	1	0.3	(0.0-1.8)	1	0.3	(0.0-1.8)
Tachycardia	1	0.3	(0.0-1.8)	0	0.0	(0.0-1.0)
Arrythmia	0	0.0	(0.0-1.8)	1	0.3	(0.0-1.1)
Bradycardia	1	0.3	(0.0-1.8)	0	0.0	(0.0-1.0)
Thrombus	4	1.3	(0.4-3.4)	0	0.0	(0.0-1.0)
Spasm	4	1.3	(0.4-3.4)	0	0.0	(0.0-1.0)
Balloon Breakage Over Pressure	2	0.7	(0.1-2.4)	0	0.0	(0.0-1.0)
Pericardial Tamponade	1	0.3	(0.0-1.8)	0	0.0	(0.0-1.0)
Pulmonary Edema	1	0.3	(0.0-1.8)	1	0.3	(0.0-1.1)
Vasovagal Response	2	0.7	(0.1-2.4)	0	0.0	(0.0-1.0)
Gastrointestinal Bleeding	1	0.3	(0.0-1.8)	0	0.0	(0.0-1.0)
Angina	4	1.3	(0.4-3.4)	18	6.0	(3.1-8.8)
Total	81			28		
Any Complication	57	18.9	(14.7-23.8)	26	8.6	(5.1-12.2)

Patients Free of Any Complication:

218/301 72.4% 95% C.I. = (67.0% - 77.4%)

‡ All Confidence Intervals were determined using Statxact exact binomials.

† Minor Dissections are those that are Types A-C as defined by NHLBI criteria, below. Those of Type D, E or F are Major Dissections.

Type A: Minor radionucleides within the lumen during contrast injection with minimal or no persistence after dye clearance.
Type B: Parallel tracts or double lumen separated by radiolucent area during contrast injection with minimal or no persistence after dye clearance.
Type C: Extraluminal cap with persistence of contrast after dye clearance from the coronary lumen.
Type D: Spiral luminal filling defects.
Type E: New, persistent filling defects.
Type F: Those non-A through E types that lead to impaired flow or total occlusion; no distal antegrade flow.

i. Vascular Complications
(N=301 Procedures)

	n	%	95% C.I.
Hematoma	8	2.7	(1.2 - 5.2)
Transfusion	(4)	1.3	(0.4 - 3.4)
Surgical Repair	(1)	0.3	(0.0 - 1.8)
Medical or None	(3)	1.0	(0.2 - 2.9)
Pseudoaneurysm	1	0.3	(0.0 - 1.8)
Transfusion	(1)	0.3	(0.0 - 1.8)
Cerebrovascular Event	1	0.3	(0.0 - 1.8)
Total	10	3.3	(1.6 - 6.0)

ii. Major Cardiac Events

Major In-Hospital Cardiac Events
(N=297 patients)

	n	%	95% C.I.
Death	0	0.0	(0.0 - 1.0)
Non-fatal MI	7	2.4	(1.0 - 4.8)
CABG	4	1.3	(0.0 - 3.4)
Repeat Intervention	0	0.0	(0.0 - 1.0)
Any Event	11	3.7	(1.9 - 6.5)

Major Out-of-Hospital Cardiac Events
(N=233 Patients*)

	n	%	95% C.I.
Death	3	1.3	(0.0 - 3.7)
Non-fatal MI	3	1.3	(0.0 - 3.7)
CABG	11	4.7	(2.4 - 8.3)
Repeat Intervention	32	13.7	(9.6 -18.8)
PTCA	(28)	12.0	(8.1 -16.9)
DCA	(4)	1.7	(0.0 - 4.3)
Any Event	49	21.0	(16.0 -26.8)

* Only Initially Clinically Successful patients were followed.

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b. Deaths

Three deaths occurred in this 297 patient study group. Summaries of these cases follow:

i. Twenty-one days post discharge (39 days after successful PTCA of a graft) a 74 year old male presented to the emergency room with congestive heart failure. The patient developed a metabolic encephalopathy and, at the wishes of the family and himself, was not resuscitated from cardiac arrest occurring at 35 days.

ii. A 64 year old female underwent successful PTCA of a 68% stenosis of the mid RCA with a post-angioplasty result of 0%. The patient had severe peripheral vascular disease and access through the right femoral artery was difficult. Against medical advice, the patient discharged herself the day after her PTCA procedure and sought treatment for her peripheral vascular disease the following day through admittance to another hospital where she underwent peripheral vascular surgery and died after surgery.

iii. A 57 year old male with a history of diabetes, high blood pressure and hypothyroidism was admitted having an acute inferior myocardial infarction. He underwent successful PTCA for mid and distal RCA lesions. It was planned to treat an LAD lesion five days later. Late in this admission, he developed mild symptoms of congestive heart failure which responded to the administration of Lasix. He was discharged the next day because he wanted to go home that day and return for the angioplasty of his LAD. It was felt as though his condition was stable enough to do that. Early evening of the day he was discharged the patient was admitted to another hospital in cardiac arrest and died shortly thereafter.

c. Device Malfunctions

There were 344 Oracle™ Micro catheters used in the 301 procedures. A list of the device malfunctions which occurred during the study follows:

Dilatation Performance Malfunctions
(N=344 Catheters Used)

	n	%	95% C.I.
Balloon Burst - over pressurization	2	0.6	(0.1-2.1)
Failure to Track Over the Guidewire	1	0.3	(0.0-1.6)
Slow Balloon Deflation	2	0.6	(0.1-2.1)
Total	5	1.5	(0.5-3.4)

Imaging Performance Malfunctions
(N=344 Catheters Used)

No Image Upon Connection	13	3.8	(2.0-6.4)
Image Failure During Procedure	25	7.3	(4.8-10.5)
Total	38	11.0	(7.9-14.9)

There were no patient injuries as a result of these device malfunctions.

3. Effectiveness Data

a. Definitions

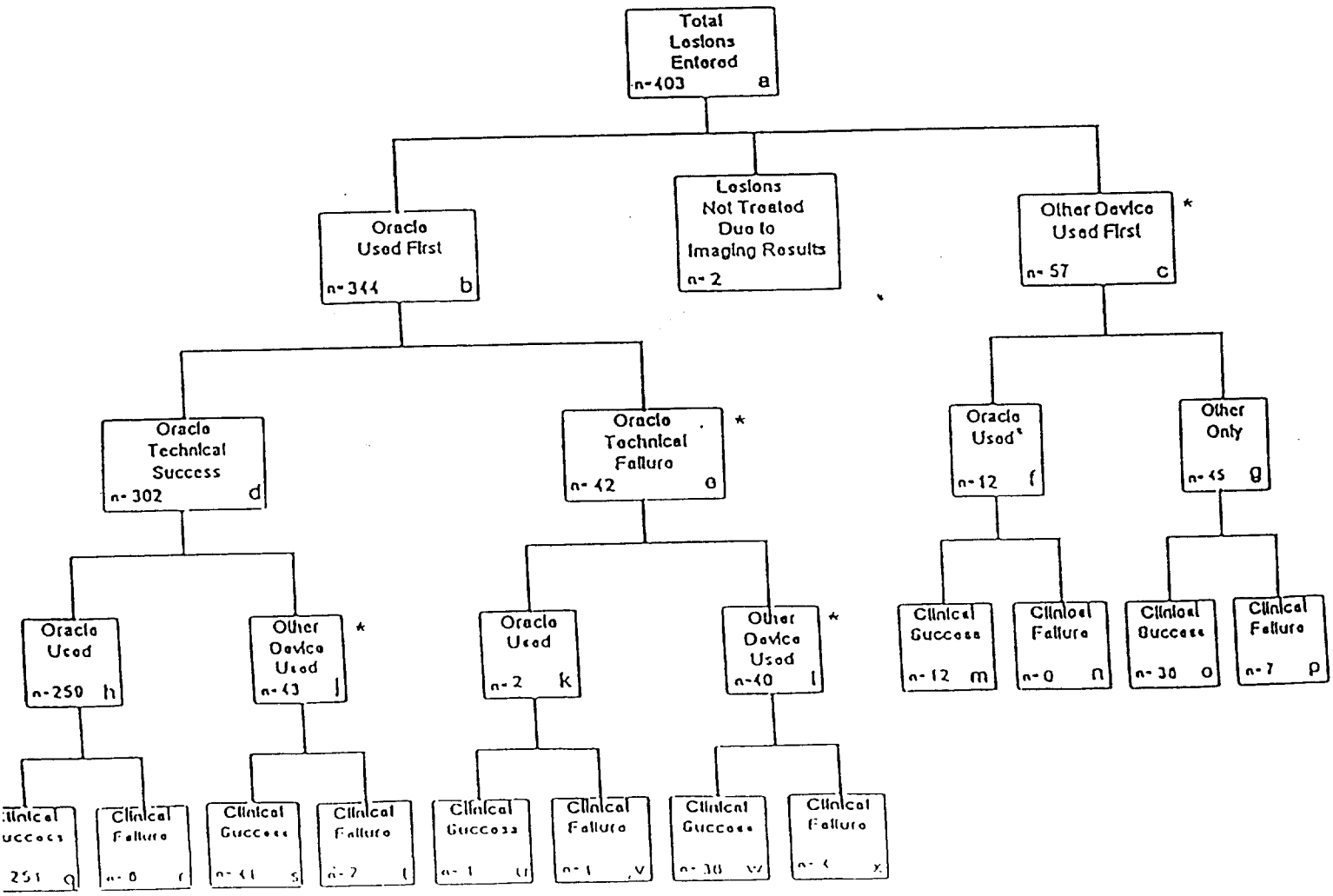
Technical Success - All of the following must occur:

The PTCA wire must cross the lesion
The Oracle™ Micro must be used first
The Oracle™ Micro must cross the lesion
There must be no mechanical failure
There must be no other device used due to any complication

Clinical Success - All of the following must occur:

A reduction in percent stenosis of ≥ 20%
A residual stenosis of ≤ 50%
No acute patient complications, and no in-hospital reclosure, emergent reintervention, bail-out stenting, myocardial infarction (Q wave or non-Q wave) or death

b. Lesion Results Flow Chart



c. Clinical Success Rates

Rate of Clinical Success of Lesions Treated with Oracle™ Micro First:

328/344 95.3% 95% C.I. = (92.6%, 97.3%)

Rate of Technical and Clinical Success of Lesions Treated with Oracle™ Micro First:

292/344 84.9% 95% C.I. = (80.7%, 88.5%)

Rate of Stand-Alone Clinical Success for Oracle™ Micro

251/344 73.0% 95% C.I. = (67.9%, 77.6%)

c. Details of Lesion Results Flow Chart

i. Other Devices Used First ("c" on Lesion Results Flow Chart)

PTCA Catheter, legally marketed		42
Directional Coronary Atherectomy (DCA)		13
Laser		1
PTCA terminated, CABG surgery		1
	Total	57 Lesions

ii. Reasons for Oracle™ Micro Technical Failures ("e" on Lesion Results Flow Chart)

Mechanical Problem		2
Dissection Requiring Other Device		12
Perfusion Catheter	10	
Long Balloon Catheter	1	
DCA	1	
Lesion Not Crossed		28
Balloon Ruputure (over pressure)		2
	Total	44 Failures (42 Lesions)

iii. Other Devices following Oracle™ Micro Technical Failure ("l" on Lesion Results Flow Chart)

PTCA Catheter, legally marketed		38
DCA		1
Laser		1
	Total	40 Lesions

iv. Other Devices following Oracle™ Micro Technical Success ("j" on Lesion Results Flow Chart)

PTCA Catheter, legally marketed		38
DCA		5
	Total	43 Lesions

v. Reasons for Oracle™ Micro Clinical Failure ("r" on Lesion Results Flow Chart)

Incomplete Dilatation		1
Clinical Complication		7
	Total	8 Lesions

e. Patient Accountability

There were 257 patients in which one or more lesions were attempted with the Oracle™ Micro only. There was at least one sucessfully treated lesion in 206 (80.2%). There were 221 patients in which all lesions were attempted with the Oracle™ Micro only. All lesions were successfully treated in 180 patients (81.4%).

	N	%	95% C.I.
Patients Entered	301		
One or More Oracle™ Micro Only Lesions	257		
One or More Lesions Successful	206	(80.2%)	(74.8-84.9)
All Oracle™ Micro Lesions	221		
All Lesions Successful	180	(81.4%)	(75.7-86.4)

f. Evaluation of Gender Bias

The patient population enrolled in this clinical study was 70.1% male, a proportion similar to other recent interventional studies. Higher incidence rates of coronary artery disease in men have long been reported by investigators researching the epidemiology of the disease (Douglas, PS (ed): Cardiovascular Clinics 19:129-145). Acute success rates did not differ significantly by patient gender:

Clinical Success of Lesions Treated with Oracle™ Micro First:

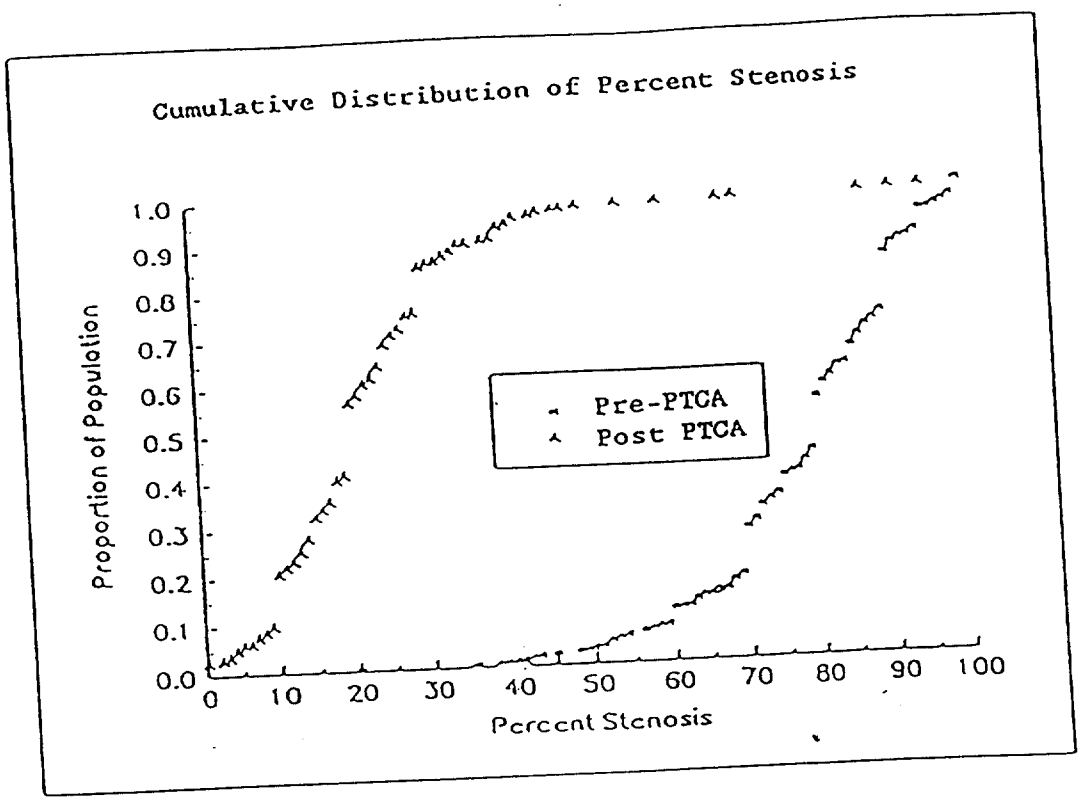
	n/N	%	95% C.I.
Males	202/211	95.7	(92.1-98.0)
Females	85/ 90	94.4	(87.5-98.2)

Technical and Clinical Success of Lesions Treated with Oracle™ Micro First:

	n/N	%	95% C.I.
Males	178/211	84.4	(78.7-89.0)
Females	78/ 90	86.7	(77.9-92.9)

g. Acute Angiographic Results

The angiographic data of lesions treated with the Oracle™ Micro PTCA Catheter in this investigation, both prior to and following PTCA, are summarized below:



Angiographic Percent Stenosis.

	Mean	s.e.
Pre-PTCA (N=402 Lesions)	78.6%	13.4%
Post-PTCA (N=401 Lesions)	22.2%	14.3%

h. Imaging Performance

	N	%	95% C.I.
Catheters Used	344		
Catheters Failing to Image	13	3.8	(1.6 - 5.9)
Catheters Returned/not Used	(7)		
Catheters Used w/ No Imaging	(6)		
Catheters Successfully Providing an Image	331	96.2	(94.1-98.4)
Catheters Failing During Procedure	25	7.3	(4.4 -10.2)
Catheters With No Failure	306	89.0	(95.6-89.8)

	n/N	%	95% C.I.
Cases Attempted	301		
Cases Performed with Failed Catheters	6		
Cases Terminated Prior to Imaging	16		
Cases With Images Subject to Interpretation	279/301	92.7	(89.1-95.4)
Cases Interpreted	256/301	85.0	(80.5-88.9)
Cases with no Imaging/Interpretation Failures	242/301	80.4	(75.5-84.7)

Reasons for Failure to Interpret Ultrasound Images

Arterial diameter too small/ Lesion not crossed	11
Device mishandled during use	1
Procedure terminated prior to imaging due to exchange to competitive catheter	4
Physician unable to visualize or analyze image for interpretation	1
Ringdown artifact incorrectly subtracted, battery not charged prior to using imaging system, electrical noise in cath lab prevented image interpretation	8
Images inadequate to interpret	1
Imaging stopped during procedure	11
Not Recorded	2
Total	39

i. Use of Ultrasound Image Information

In order to obtain qualitative data on the use and content of the intravascular image, the physician was asked whether the ultrasound image changed the impression of the results obtained angiographically. An explanation for a positive response was also requested. The explanation provided was used to determine whether the ultrasound image changed the course of therapy the patient received. The following responses were given:

		N	%	95% C.I.
Cases Attempted		301		
Cases Interpreted		256	85.0	(80.9-89.2)
Change in Therapy		106	32.0	(29.7-40.7)
Change in balloon size	13			
Change in inflation strategy	89			
Did not dilate an angiographically apparent lesion	5			
Dilated an angiographically questionable lesion	8			
Changes in Impression		101	33.6	(28.1-39.0)
More disease than expected	65			
Calcification seen which was not appreciated on angiography	31			
Others	45			
Intimal fracture or dissection visible				
Better assessment of morphology				
Additional disease area identified				
Assisted in determining percent stenosis				
Identified dissection not seen by angiography				

j. Quantitative Ultrasound and Angiographic Data

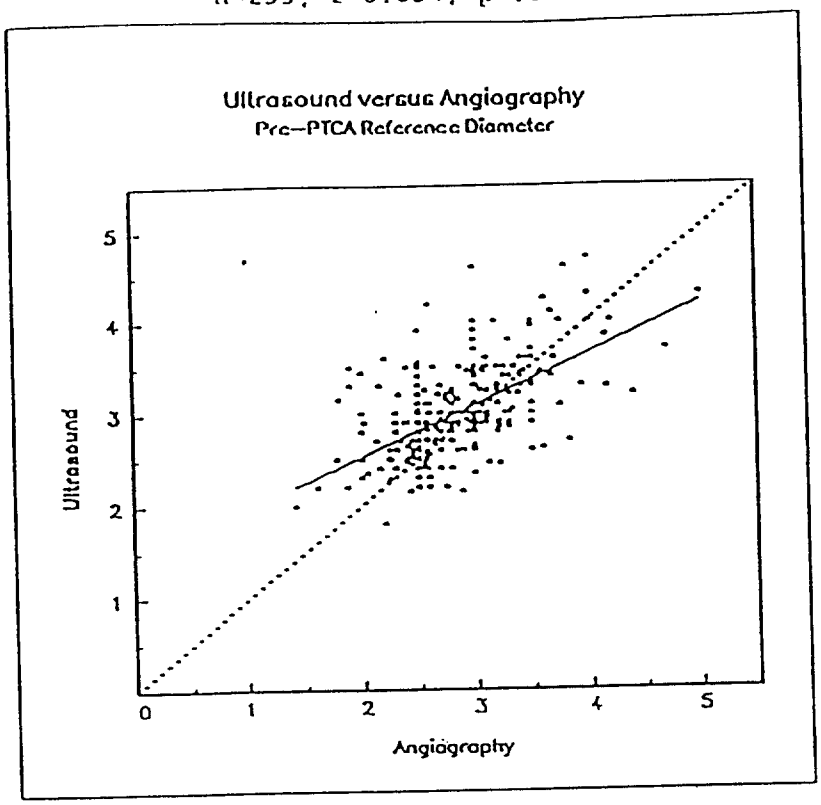
In order to evaluate the correlation between the angiographic data and the ultrasound images, correlation analysis was performed on the following variables:

Pre-PTCA Reference Diameter
Post-PTCA Reference Diameter
Post-PTCA Lesion Diameter
Post-PTCA Percent Stenosis

Pre-PTCA Lesion Diameters were not analyzed due to the inability to image the lesion prior to PTCA. Angiographic and ultrasound data are compared below:

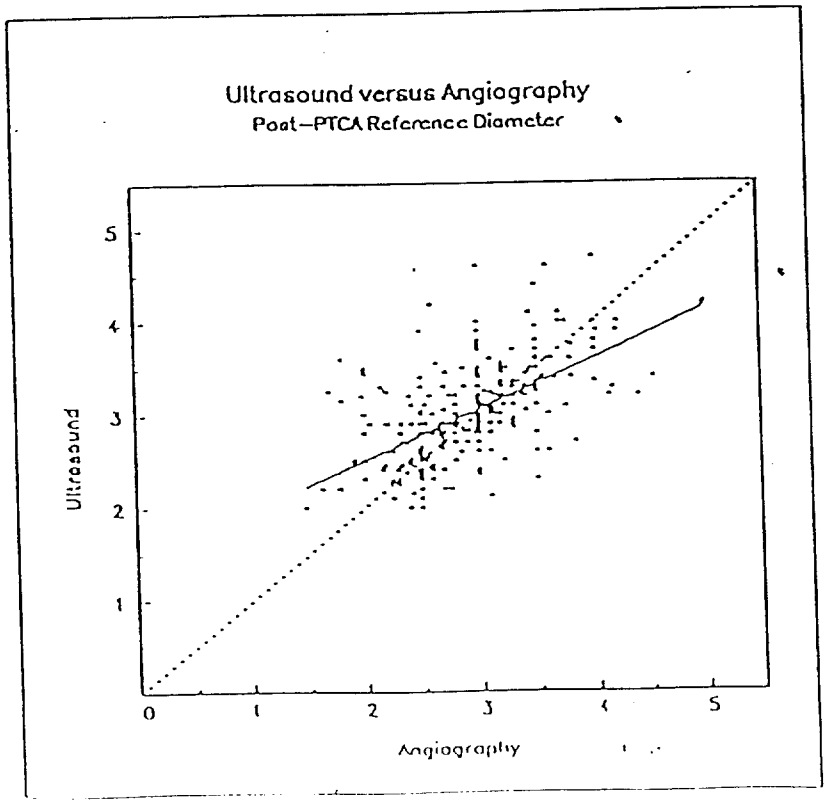
Pre-PTCA Reference Diameter

n=235, r=0.634, p=.0001



Post-PTCA Reference Diameter

n=250, r=0.635, p=.0001



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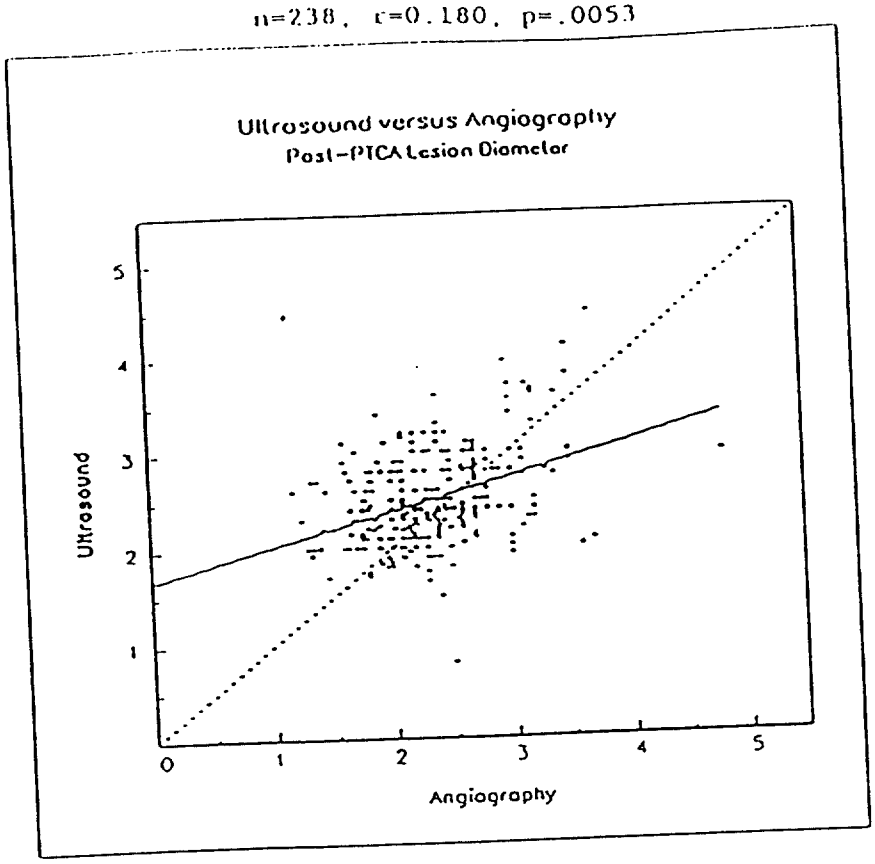
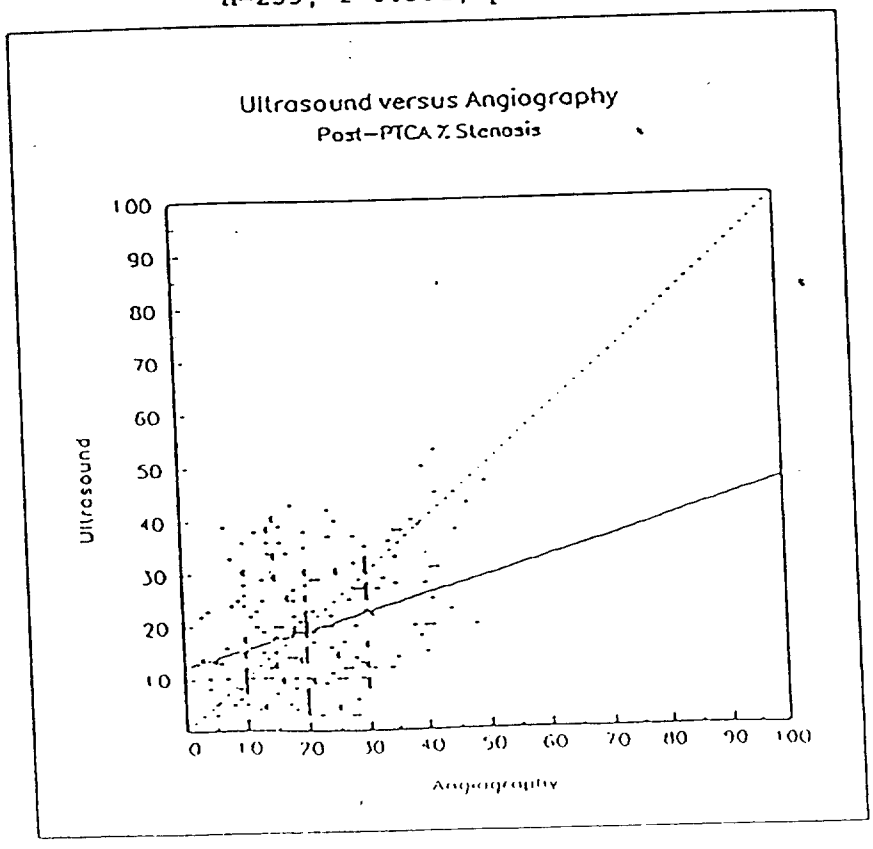
Post-PTCA Lesion Diameter

n=238, r=0.180, p=.0053



Post-PTCA Percent Stenosis

n=235, r=0.332, p=.0001



k. Discussion of Correlation Data

A poor correlation between angiography and intravascular ultrasound images in diseased arteries is expected based on existing published literature on intravascular ultrasound. The two techniques are fundamentally different in that angiography provides a planar projection as opposed to the tomographic image provided by ultrasound.

Nissen, et al, (Circulation 84: September, 1991) reported that for diseased, non-circular coronary arteries, only moderate correlation is obtained (r=.77) despite rigorous attempts at obtaining concordant angiographic and ultrasonic imaging views. Higher correlations were obtained for normal arteries, however, the degree of correlation decreased with the amount of disease and vessel non-circularity.

Tobis, et al. (Circulation 83: March 1991) found very poor correlations between angiography and intravascular ultrasound post-PTCA. Measurements of the reference segment and the lesion segment were obtained by both intravascular ultrasound and angiography. Correlation for the reference segments was r=0.26.

1. Follow-up Results

i. Follow-up studies consisted of telephone contact, office visits or hospital examinations. Initially clinically successful patients treated with the Oracle™ Micro PTCA Catheter were followed. The mean follow-up period was 149 days.

Telephone follow-up data were collected by nurses at the investigational site. The following history and physical information was collected:

Current Status assessed by Canadian Heart Association (CHA) Classification of Symptoms
Changes in symptoms post-discharge
Medical history post-discharge (any adverse events of repeat interventions)

Office follow-up studies consisted of the above information in addition to the following:

ECG
Stress tolerance testing or thallium exercise studies
Physical Examination

Hospital follow-up included angiographic study when medically indicated, in addition to the information listed above. As shown, not every evaluative method was used for every patient.

	N	%	95% C.I.
Patients Entered	297		
Initial Clinical Successes	251/297	84.5	(79.9-88.4)
Number with Follow-up	233/251	92.8	
Hospital	66		
Office	164		
Telephone	3		
Number Without Follow-up	18/251	7.7	
Compliance not obtained to date	13		
Lost to Follow-up	5		
Symptoms of Restenosis			
CHA Classification	44/197	22.3	(16.7-28.8)
Unchanged	36		
Worsened	8		
ECG Abnormality	29/194	14.9	(10.3-20.8)
Positive Stress/Thallium Test	33/140	23.6	(16.8-31.5)
Positive Angiogram	43/ 59	72.9	(59.7-83.6)
Repeat Intervention	32/233	13.7	(9.6-18.8)
PTCA	28		
DCA	4		
Adverse Events	17/233	7.3	(4.3-11.4)
MI	3		
Death	3		
CABG	11		

ii. Freedom From Events During Follow-Up
(N=233 Patients followed)

	N	%	95% C.I.
Event (death, CABG, MI, Repeat Intervention)	49/233	21.0%	(16.0-26.8)
Event and/or Angiographic Evidence	56/233	24.0%	(18.7-30.0)
Event and/or Angiographic Evidence and/or Symptoms of Restenosis*	95/233	40.8%	(34.4-47.4)

* "Symptoms of Restenosis" is defined as CHA Classification unchanged or worsened from pre-PTCA, abnormal ECG as compared to post-PTCA or a positive Stress/Thallium study.

m. Summary of Results of Clinical Studies

i. Acute Success

Acute Clinical Success (Lesions Treated with Oracle™ Micro First):	n/N 328/344	% (95.3%)	95% C.I. (92.6-97.3)
Acute Technical and Clinical Success (Lesions Treated with Oracle™ Micro First:	292/344	(84.9%)	(80.7-88.5)

ii. Imaging Success

Cases in Which an Interpretable Ultrasound Image was Successfully Obtained:	256/301	(85.0%)	(80.5-88.9)
Ultrasound Images Led To:			
Change in Therapy:	106/301	(35.2%)	(29.8-40.9)
Change in Impression:	101/301	(33.6%)	(28.2-39.2)

iii. Acute Complications

Acute Vascular Complications (N=301)	n	%	95 % C.I.
Hematoma	8	2.7	(1.2 - 5.2)
Transfusion	(4)	1.3	(0.4 - 3.4)
Surgical Repair	(1)	0.3	(0.0 - 1.8)
Medical or None	(3)	1.0	(0.2 - 2.9)
Pseudoaneurysm	1	0.3	(0.0 - 1.8)
Transfusion	(1)	0.3	(0.0 - 1.8)
Cerebrovascular Event	1	0.3	(0.0 - 1.8)
Total	10	3.3	(1.6 - 6.0)

Acute Major Cardiac Events (N=301)	n	%	95 % C.I.
Death	0	0.0	(0.0 - 1.0)
Non-fatal MI	7	2.4	(1.0 - 4.8)
CABG	4	1.3	(0.0 - 3.4)
Repeat Intervention	0	0.0	(0.0 - 1.0)
Any Event	11	3.7	(1.9 - 6.5)

	n/N	%	95% C.I.
Patients Free of Any Acute Complication	218/301	72.4	(67.3-77.6)

iv. Follow-up Results

Follow-Up Events (N=233)	n	%	95% C.I.
Death	3	1.3	(0.0 - 3.7)
Non-fatal MI	3	1.3	(0.0 - 3.7)
CABG	11	4.7	(2.4 - 8.3)
Repeat Intervention	32	13.7	(9.6 -18.8)
PTCA	(28)	12.0	(8.1 -16.9)
DCA	(4)	1.7	(0.0 - 4.3)
Any Event	49	21.0	(16.0-26.8)
Event/ Angiographic Evidence/ Symptoms of Restenosis*:	95/233	40.8%	(34.4-47.4)

* "Symptoms of Restenosis" is defined as CHA Classification unchanged or worsened from pre-PTCA, abnormal ECG as compared to post-PTCA or a positive Stress/Thallium study. Mean time to follow-up-159 days.

X. Conclusions Drawn From Studies

The results of the laboratory and animal testing demonstrate that the Endosonics Oracle™ Micro PTCA Catheter has the appropriate physical and performance characteristics for its intended use, as stated in the labeling.

The biocompatibility tests demonstrate that the materials used in the device are biocompatible for short-term blood contact.

The clinical study conducted indicate with reasonable assurance that the Endosonics Oracle™ Micro PTCA Catheter is safe and effective for the treatment of patients with coronary artery disease. Additionally, the study demonstrates that the Endosonics Oracle™ Micro PTCA Catheter, when used with the Cathscanner® Intravascular Ultrasonic Imaging System as an adjunct to conventional angiographic procedures, can provide images of the vessel lumen and wall structures.

XI. Panel Recommendations

The Circulatory System Devices Advisory Panel reviewed this application at a public meeting on April 12, 1993. The panel recommended that the application be found Not Approvable, based on the lack of clinical data for the Endosonics Oracle™ Micro PTCA Catheter at that time. The application included 86 subjects treated with the subject device, and the panel requested that the results of 200 subjects treated with the Endosonics Oracle™ Micro PTCA Catheter, with clinical follow-up to two months, be submitted to demonstrate the safety of the catheter.

XII. FDA Decision

FDA concurred with the recommendations of the Circulatory System Devices Advisory Panel. A not approvable letter to that effect was issued to the applicant on September 24, 1993. On December 27, 1993, and September 6, 1994, the applicant submitted amendments to the application providing the information required by FDA. The amendments were reviewed by FDA and found to sufficiently demonstrate the safety and effectiveness of the device.

A Good Manufacturing Practices (GMP) Inspection, accomplished on August 4, 1993, revealed that the company was in compliance with GMP regulation (21 CFR, Part 820).

XIII. Approval Specifications

Continued approval of the device is contingent upon the submission of postapproval reports to the Food and Drug Administration as described in the Conditions of Approval enclosed in the approval letter (Attachment A). A copy of the draft final instructions for Use is attached (Attachment B).

Physician Guide

and

Package Insert

Endosonics Oracle™ Micro™ PTCA Catheter

MANUFACTURED BY:

ENDOSONICS CORPORATION
6616 Owens Drive
Pleasanton, CA 94588
(510) 734-0464

DISTRIBUTED IN U.S.A. BY:

ENDOSONICS CORPORATION
6616 Owens Drive
Pleasanton, CA 94588
(510) 734-0464

CAUTION:

1. U.S. Federal Law restricts this device to sale by or on the order of a physician.
2. Prior to use, read this entire package insert.

PACKAGE INSERT

DESCRIPTION:

The Endosonics Oracle Micro PTCA Catheter is a double-lumen catheter with a balloon near the distal tip and an ultrasound imaging transducer just proximal to the balloon. One lumen is used for inflation of the balloon, and the other lumen permits the use of a coronary guide wire to facilitate the advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an expandable segment of known diameter and length at a specific pressure.

The catheter is available with a 2.0mm balloon, a 2.5mm balloon, a 3.0mm balloon, or a 3.5mm balloon. The catheter has a 3.5F shaft along the entire shaft length.

The Cathscanner ultrasound transducer is located immediately proximal to the balloon. This transducer will provide a cross-sectional image of the tissue surrounding the imaging array. There are two radiopaque markers; one immediately under the imaging array at the proximal end of the balloon and the other at the center of the balloon.

A three-arm adapter is on the proximal end of the catheter. The sideport of the adapter is connected to the balloon lumen, and has a Luer-lock fitting for attaching the catheter to an inflation device. The guide wire port is continuous with the inner lumen of the catheter. The third arm contains a permanent cable which connects the imaging transducer to the external electronic imaging system. The inner lumen allows for free movement of a conventional coronary guide wire equal to or smaller than 0.014 inch.

INDICATIONS AND USAGE:

Percutaneous transluminal coronary angioplasty (PTCA) is indicated in patients with coronary artery disease who are acceptable candidates for coronary artery bypass graft surgery, and who meet one of the following selection criteria:

(1) Single vessel atherosclerotic coronary artery disease that is discrete and accessible to a dilatation catheter.

(2) Multiple vessel coronary artery disease under certain circumstances.

(3) Coronary artery disease of the native coronary arteries and/or coronary artery bypass grafts of some patients who have previously undergone coronary artery bypass graft surgery, who have recurrence of symptoms, and (a) progression of disease, or (b) stenosis and closure of the grafts.

The Endosonics Oracle™ Micro PTCA Catheter is further indicated for use following balloon dilatation as an adjunct to conventional angiographic procedures to provide:

(1) An image of the vessel lumen and wall structures.

(2) Dimensional measurements from the image.

CONTRAINDICATIONS

- o Candidates not acceptable for coronary artery bypass graft surgery.
- o Unprotected left main coronary artery disease.
- o Previously diagnosed episodes of coronary artery spasm.

ADVERSE EFFECTS

Potential adverse effects include, but are not limited to, the following:

- o Dissection of the coronary artery.
- o Injury to the coronary artery.
- o Total occlusion of the coronary artery.
- o Acute myocardial infarction.
- o Unstable angina pectoris.
- o Ventricular fibrillation.
- o Embolization
- o Restenosis of the dilated artery.
- o Coronary Artery Spasm
- o Hemorrhage or Hematoma
- o Death.

In the event of a serious complication necessitating emergency coronary artery bypass graft surgery, patients who have previously undergone this surgery have a higher mortality rate than patients who have never had coronary artery bypass graft surgery.

- This device is designed and intended for one time use only. Do not resterilize and/or reuse it.
- The dilatation catheter should only be used when the inflation device is attached. Failure to do so may result in balloon rupture due to over-pressurization.
- Careful inspection prior to use should verify that the catheter has not been damaged in shipment and that its size (full diameter should be no larger than the diameter of the artery just distal or proximal to the stenosis), shape, and condition are suitable for the specific procedure for which it is to be used.
- Prior to inserting the dilatation catheter into the patient, it should be tested as described in the Information for Use section. In vivo balloon pressure should never exceed the Rated Burst Pressure.
- The short- and long-term biological effects of using an inflation pressure above that necessary to reach nominal balloon diameter are not known.

PRECAUTIONS

- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be immediately performed in the event of a potentially injurious or life-threatening complication. A cardiac surgery team should be on alert while a PTCA procedure is being performed.
- This catheter system should be used only by physicians who are experienced in coronary arteriography and who have received training in the technique of PTCA.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon when it is inside a patient.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be continued for a period of six months after the procedure.
- When the catheters are in the body, they should only be manipulated while they are under fluoroscopic observation with radiographic equipment that provides high-quality images.
- The Endosonics Oracle™ Micro PTCA Catheter device is a delicate scientific instrument and should be treated as such. Always observe the following precautions:

  Protect the catheter tip from impact and excessive force.

  Do not cut, crease, knot, or otherwise damage the catheter.

  Protect the electrical connections from exposure to fluid.

  If a guidewire is used, the outside diameter along the entire length should not exceed 0.014 inches.

  During use, ensure that the placement of the catheter does not preclude blood flow through the vessel.

MATERIALS REQUIRED FOR PTCA WITH THE ENDOSONICS Oracle Micro SYSTEM.

Quantity	Item Description*
1	0.035 or 0.038 x 145 cm guide wire
1	0.014 or smaller x 145 cm guide wire
1	7 to 9F arterial sheath and dilator set (for the femoral approach only)
1	Introducer catheter
2 to 3	Femoral or brachial guiding catheters in appropriate size and configuration for the selected coronary artery (ID must be at least 0.078 inch).
1	Hemostatic side-arm adapter
1	Small vial of 50% contrast medium
1	Inflation device for balloon inflation
1 to 2	Oracle Micro coronary balloon dilatation catheter(s). (The dilatation catheter is selected according to the severity of the stenosis and the native vessel size. The inflated diameter of the balloon should approximate the coronary artery diameter, and should never exceed the diameter of the coronary artery proximal and distal to the stenosis. In instances of severe stenosis, a smaller balloon may be needed to begin the dilatation process, and it may then be replaced with a larger balloon to effect a successful dilatation.)

* The following materials are single-use item only.

INFORMATION FOR USE

INSPECTION PRIOR TO USE:

Prior to angioplasty, all equipment to be used for the procedures, including the dilatation catheter, should be carefully examined to verify proper performance. It is imperative that the balloon of the dilatation catheter be tested to the maximum pressure to be used during the procedure and that its inflation/deflation time be checked.

PREPARATION OF THE DILATATION CATHETER:

To properly prepare the catheter for use, the following steps should be completed:

1. Filling the Inflation Device

   a. Prepare the inflation device according to the manufacturer's instructions.

   b. Purge the system of air.

2. Filling the Balloon with Contrast Solution to Displace Air

   a. Prepare a mixture of 50/50% contrast media and sterile saline.

   b. Aspirate 4 cc of contrast mixture into a 20cc or larger syringe.

   c. Attach the syringe to the balloon leg of the triple arm adapter (see figure 1).

   d. Point the syringe nozzle downward and aspirate, pulling the plunger all the way back and holding, until no bubbles appear in the syringe.

Warning: If air bubbles appear in the balloon during purging, do not flick the balloon. Orient the balloon in a downward position and reaspirate. Continue purging until bubbles no longer appear. The use of a 20cc or larger syringe will facilitate purging.

   e. Infuse the contrast mixture into the balloon, inspecting for leaks or air. Repeat aspiration, if necessary, until air bubbles are no longer present in the syringe during aspiration, or in the balloon during inflation.

   f. Release the positive pressure on the syringe plunger and allow the balloon to resume a neutral state pending connection to the inflation device.

   g. Remove the 20cc syringe and attach the inflation device to the balloon leg of the triple arm adapter. Be certain the meniscus of contrast solution is evident at the luer fittings to avoid the possible introduction of air. Finger tighten the connections.

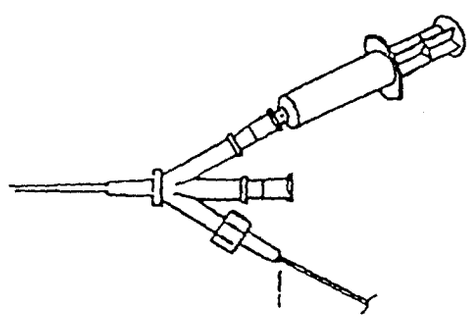


Figure 1

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PRELIMINARY TESTING OF THE BALLOON DILATATION CATHETER:

1. Prior to actual use, the dilatation catheter should be tested by inflating the balloon to the rated burst pressure(see Table I). The time required to fully inflate and deflate the balloon should also be checked.

2. Verify that the three-way stopcock connected to the inflation device and dilation catheter is open. Inflate the balloon to the maximum recommended use pressure (see Table I), and sustain that pressure for five seconds. The balloon should appear fully inflated within ten seconds of pressurization. Retract the plunger to fully deflate the balloon. It should appear fully deflated within ten seconds after applying negative pressure. Repeat the inflations and deflations for three cycles, and record the times. Retract the plunger to fully deflate the balloon, then close the three-way stopcock connected to the inflation device and dilatation catheter. Insert the balloon into the protective sheath, reopen the 3-way stopcock and set it aside until ready for use. Do not allow negative pressure to remain on the balloon catheter.

PROCEDURE TECHNIQUE:

1. To insert the catheter:

   a. Prepare and drape the selected entry site.

   b. Administer local anesthetic.

   c. Cannulate the femoral vein. Insert a 6F bipolar pacing electrode using standard techniques. The pacing electrode may be positioned in the apex of the right ventricle and placed on standby for use in the event that emergency pacing is required. The electrode also provides a spatial reference on the fluoroscopy screen.

      NOTE: If using the brachial approach, disregard substeps (d) through (j). Perform confirmatory arteriography, including intravenous heparin administration, using conventional catheterization techniques. Replace the angiographic catheters with an appropriate Brachial Guiding Catheter using a 0.035 in. or 038 in. x 145 cm guide wire. Continue with Step 2.

   d. Cannulate the femoral artery with an appropriate percutaneous needle. Remove the obturator to confirm that the needle is within the lumen of the artery.

   e. Introduce a 0.035 inch or 0.038 inch x 145 cm guide wire, flexible end first, through the needle and into the vessel. Advance the distal tip of the guide wire to the level of the diaphragm under fluoroscopy. Insert a standard angiographic catheter over the guide wire, and advance it to the arch of the aorta.

      NOTE: Never advance a guide wire if resistance is encountered without first determining the cause of resistance by fluoroscopy.

   f. Anticoagulate the patient with intravenous heparin. Perform baseline coronary arteriography to confirm the severity of the stenosis and to verify that the patient still meets the indication criteria for PTCA.

   g. Flush the guiding and introducer catheters with normal saline. Insert the introducer catheter into the guiding catheter.

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h. Using standard percutaneous techniques, replace the angiographic catheter with a 7 to 9F guiding catheter. Insert the guiding catheter through the sheath over a guide wire. Advance to the descending aorta under fluoroscopy.

i. Continue advancing the guiding catheter to the ascending aorta under fluoroscopy. The guide wire and introducer catheter should precede the tip of the guiding catheter until its tip is around the aortic arch.

j. Start withdrawing the guide wire and introducer catheter together as the guiding catheter is advanced into position. Remove the guide wire and introducer catheter.

2. Attach a coronary manifold to the side arm of the hemostatic side-arm adapter with a short connecting tubing (Figure 2). Flush the device with normal saline to eliminate any air. To properly flush the valve arm, use a thumb or finger to cap the fitting that connects the arm to the guiding catheter. Open the valve, and flush saline through the device. Close the valve, and connect the hemostatic side-arm adapter to the guiding catheter.

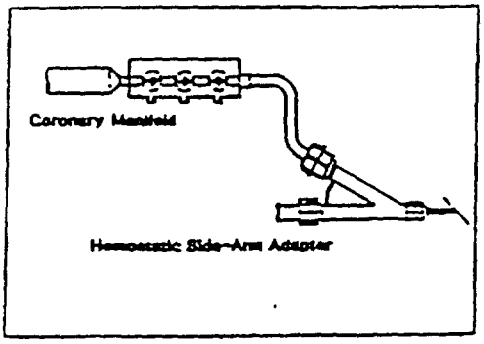

Figure 2 Connecting the hemostatic side-arm adapter to a coronary manifold.

3. Aspirate the guiding catheter to free any trapped air. Flush the guiding catheter with normal saline, fill it with contrast medium, and selectively engage it in the appropriate coronary ostium. Confirm the catheter position by arteriography.

4. Attach the connector on the Oracle Micro catheter to the Patient Interface Module on the Cathscanner Imaging System. Determine that there is an image on the screen. Consult the system manual for further information.

5. Prior to inserting the Oracle Micro catheter into the guiding catheter; join a second hemostatic side-arm adapter to a coronary manifold with a short connecting tubing (Figure 3). Flush, and fill the side-arm with normal saline as previously described in Step 2. Connect the hemostatic side-arm adapter to the guide wire port of the three-arm adapter of the dilatation catheter, carefully passing the guide wire through the hemostatic valve. Flush, and fill the inner member lumen of the catheter with normal saline. (Optional: The second side-arm adapter, to the guide wire port, may be removed to allow for increased movement of the guide wire.) Loosen the thumb screw of the adapter, and open the saline stopcock on the manifold so that fluid drips from the thumbscrew. Position the guide wire so that it is inside the dilatation catheter as far as it will go. Tighten the thumb screw so that the valve closes firmly around the guide wire, and close the saline stopcock on the manifold. Pull the negative pressure to collapse the balloon with the inflation device, and slide the peel-away introducer over the distal tip of the Oracle Micro catheter. Shape the guide wire tip into the desired configuration and retract the guide wire back into the introducer for protection during insertion into the guiding catheter.

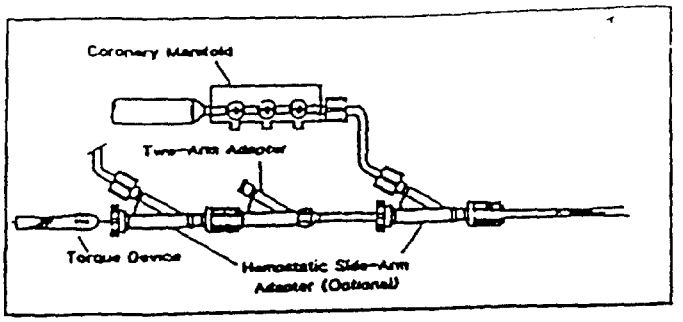

Figure 3 Connecting a second hemostatic side arm adapter and a guide wire torque device. Advancing the Oracle Micro to the tip of the guide catheter.

6. Loosen the knurled screw fitting on the hemostatic side-arm adapter which is attached to the guiding catheter so that it is possible to pass the dilatation catheter wire through the valve. Then introduce the dilatation catheter into the guiding catheter. It is imperative that the balloon be fully deflated during this process.

7. Re-tighten the fitting, after the dilatation catheter has been inserted at least 30 to 40 cm into the guiding catheter, to create a seal around the dilatation catheter that does not inhibit movement of the catheter. This will allow continuous recording of proximal coronary artery pressure. Advance the dilatation catheter and guide wire to the tip of the guiding catheter (Figure 3).

   WARNING: It is important that the valve be closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon.

   Slip the Torque Device over the end of the guide wire, and tighten it securely to the mandrel (Figure 3). Keep the valve of the guide wire hemostatic side-arm adapter closed when the guide wire is in the catheter. When the valve is appropriately closed, intentional movement of the wire is not inhibited.

8. Begin recording of the ultrasound images.

9. Advance the guide wire and dilatation catheter, under fluoroscopy, out of the tip of the guiding catheter, and select the desired coronary artery. Continue advancing the guide wire to and then across the stenosis while frequently confirming its position with contrast injections through the guiding catheter. The dilatation catheter may be continually advanced along with the guide wire during insertion and wire maneuvering. The spring tip of the guide wire may be rotated to facilitate the processes of vessel negotiation and crossing the stenosis by slowly turning the torque device (Figure 4).

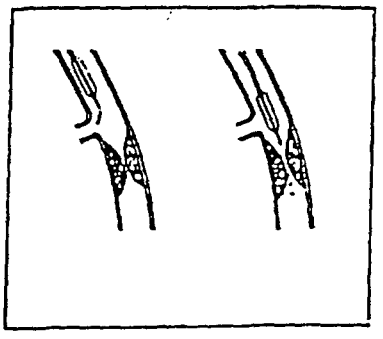

Figure 4 Rotation of the guidewire tip, by turning the proximal torque device, may be needed for vessel selection, branch vessel negotiation, and crossing of the stenosis.

10. Hold the guide wire stationary, and advance the dilatation catheter over the guide wire and into the stenosis. The radiopaque balloon marker and a very low pressure (10 to 20 psi) balloon inflation should be used to confirm that the indentation caused by the stenosis is centrally located within the balloon segment before proceeding with the dilatation (Figure 5).

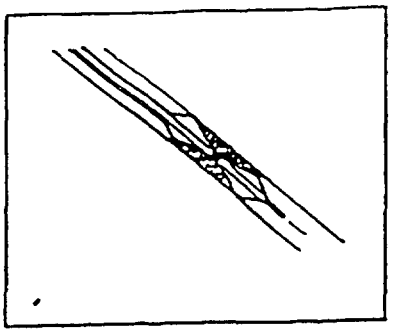

Figure 5 Test inflation prior to initial dilatation (dumbbell effect evident.)

11. Open the stopcock on the inflation device. Inflate and deflate the balloon manually by advancing and retracting the plunger. Maintain vacuum on the balloon between dilatation by closing the stopcock on the inflation device.

12. After the first inflation and each subsequent inflation, assess distal coronary blood flow by arteriography through the guiding catheter while the deflated balloon remains in the stenosis (Figure 6). Maintain the guide wire across the stenosis until distal blood flow is adequate. If distal coronary blood flow is reduced and myocardial ischemia develops before an effective dilatation is achieved, the guide wire may be advanced and maintained across the stenosis as the balloon is withdrawn, permitting reperfusion of the distal vessel.

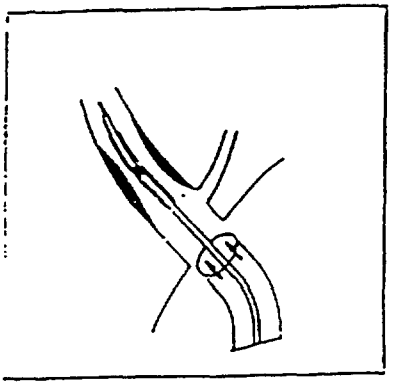

Figure 6 Injecting contrast medium through the guiding catheter with the balloon in the stenosis.

13. If desired, after the first inflation and each subsequent inflation, assess the site of dilatation by advancing the catheter further into the lesion. Do not advance the catheter if the angiographically determined vessel lumen is less than 1.2 mm. The ultrasound image of the vessel surrounding the proximal tip marker will be displayed on the Cathscanner Imaging System Display.

14. Should a significant stenosis persist, inflate the balloon to gradually increasing pressures up to the rated burst pressure or until the stenosis fails to improve with each subsequent inflation. Successive inflations of the balloon should result in dilatation of the stenosis, which is demonstrated by a decrease in the stenosis and increased contrast flow to the distal vessel.

15. Check the balloon to verify that it is fully deflated, and then close the stopcock of the inflation device to maintain the vacuum. Pull the guide wire back gently until you feel it rest against the tip of the dilatation catheter. With the balloon deflated, simultaneously withdraw the dilatation catheter and guide wire out of the coronary artery, and into the lumen of the guiding catheter. Remove the dilatation catheter from the guiding catheter through the hemostatic side-arm adapter. Close the valve of the hemostatic side-arm adapter.

    NOTE: The guiding catheter is not recommended for routine arteriography. A standard coronary angiographic catheter should be used for the postangioplasty arteriography.

16. Carefully withdraw the guiding catheter from the vessel.

17. Aspirate the sheaths, and then flush them with normal saline. Insert a standard angiographic catheter, and perform the postdilatation arteriography.

18. Remove the catheter and sheath, and achieve hemostasis by groin compression.

2.0mm Balloon (Model 55120)

BALLOON DIAMETER (mm)	INFLATION PRESSURE
1.73	1 ATM
1.78	2 ATM
1.83	3 ATM
1.86	4 ATM
1.90	5 ATM
1.95	6 ATM
1.98	7 ATM
2.03	8 ATM Rated Burst Pressure
2.08	9 ATM
2.13	10 ATM

2.5mm Balloon (Model 55125)

BALLOON DIAMETER (mm)	INFLATION PRESSURE
2.21	1 ATM
2.28	2 ATM
2.39	3 ATM
2.43	4 ATM
2.49	5 ATM
2.56	6 ATM
2.64	7 ATM
2.69	8 ATM Rated Burst Pressure
2.76	9 ATM
2.84	10 ATM

3.0mm Balloon (Model 55130)

BALLOON DIAMETER (mm)	INFLATION PRESSURE
2.69	1 ATM
2.74	2 ATM
2.79	3 ATM
2.84	4 ATM
2.89	5 ATM
2.96	6 ATM
3.02	7 ATM
3.07	8 ATM Rated Burst Pressure

3.5mm Balloon (Model 55135)

BALLOON DIAMETER (mm)	INFLATION PRESSURE
3.25	1 ATM
3.30	2 ATM
3.38	3 ATM
3.45	4 ATM
3.50	5 ATM
3.58	6 ATM
3.66	7 ATM
3.71	8 ATM Rated Burst Pressure

ULTRASONIC IMAGING SPECIFICATIONS

Center frequency	20 MHz
Maximum scan diameter	9.2mm
Maximum frame rate	10 frames per second
Ispta	0.01189 mW/cm2*
Isppa	0.000282 W/cm2*
Im	0.000774 W/cm2*

* Estimated in situ values. For measured in water values, see the System Operator's Manual.

REPACKAGING INSTRUCTIONS:

In the event the catheter must be returned for any reason, return the Oracle Micro catheter in its original package and shipping box. Contact Endosonics to receive a Return Authorization Number prior to return shipment.

WARRANTY:

Endosonics Corporation has exercised reasonable care in the manufacture of the Oracle Micro catheter. Endosonics warrants that the Oracle Micro catheters shall be free of defects in materials and workmanship upon receipt. Endosonics warranty shall not apply to these products if they have been altered or utilized in a manner not approved by Endosonics or subjected to misuse, negligence or accident. The liabilities of Endosonics arising out of supplying this product whether based on warranty or otherwise, shall in no case exceed the price of this product.

Endosonics Corporation makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the re-use of this catheter.

In addition, Endosonics Corporation assumes no responsibility or liability for incidental or consequential damages which may result from such re-use.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:

ENDOSONICS CORPORATION
6616 Owens Drive
Pleasanton, CA 94588
(510) 734-0464
(800) CATHS CV
(800) 228-4728

CVD™

GUARDIAN Coronary Dilatation Catheter

Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外径直径最大限	Model Modello Modèle Modelo Modell モデル
135 cm	3.3F / 2.6F	.014 in	3025

featuring SlyDx™ advanced coating technology

STERILE AND NONPYROGENIC

Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For one procedure only. Do not resterilize. Do not use open or damaged packages. Store in a dry, dark, cool place. Refer to accompanying Instructions for Use.

Steril. Sterilisiert mit Athylenoxid. Pyrogenfrei. Nur zum einmaligen. Gerbrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschadigten. Packungen benutzen. Trocken, dunkel und kuhl aufbewahren. Vor Gebrauch Anleitungen durchlesen.

Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'àbri de la lumiére. Lire la notice avant utilisation.

Estéril. Esterilizado con óxido de etileno. Apirógeno. Para un solo uso. No reesterilizar. No utilizar si el embalaje está abierto o deteriorado. Almacenar en un lúgar fresco, uscuro y seco. Leer las instrucciones antes de usar.

Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

殺菌　エチレン酸化ガスで殺菌。不加熱。一手段のみ。再殺菌をしないでください。開封または破れたパッケージは使用しないでください。乾燥した冷暗所に保存してください。使用につきましては、説明書を参考にしてください。

CAUTION

Federal (USA) law restricts this device to sale, distribution and use by or under order of a physician.

CONTENTS

Contents: Inhalt: Contenu: Contenido: Contenuto: 内容物:

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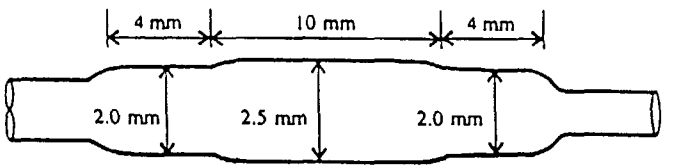
13700 Alton Parkway
Irvine, California 92618 USA
(714) 457-9546 • (800) 721-2284
Customer Service (714) 597-8197



Nominal at 12 Atmospheres

650-0191 Rev. A

Developed in conjunction with John McB. Hodgson, MD

Manufactured under one or more of the following patents:
5,295,962; 5,344,402; 5,368,566; 5,421,826; 5,470,313; 5,522,800
U.S. and foreign patents pending

CVD™ GUARDIAN

Rated Burst Pressure 16 atm

Balloon Diameter 2.0 **2.5** mm

Balloon Length 18 mm

003

CVD™ GUARDIAN Coronary Dilatation Catheter

Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外枠直径最大限	Model Modello Modèle Modelo Modell モデル
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SlyDx™ *featuring advanced coating technology*

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Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'àbri de la lumiére. Lire la notice avant utilisation.

Estéril. Esterilizado con óxido de etileno. Apirógeno. Para un solo uso. No reesterilizar. No utilizar si el embalaje está abierto o deteriorado. Almacenar en un lugar fresco, uscuro y seco. Leer las instrucciones antes de usar.

Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

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Customer Service (714) 597-8197

6504-1192 Rev A

Developed in conjunction with John McB. Hodgson, MD

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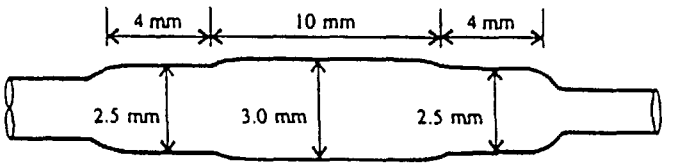
U.S. and foreign patents pending



Nominal at 12 Atmospheres

CVD™ GUARDIAN

Rated Burst Pressure 16 atm

Balloon Diameter 2.5 **3.0** mm

Balloon Length 18 mm

CardioVascular Dynamics, Inc.
PMA Real Time Review of Guardian Coronary Balloon Dilatation Catheter

October 13, 1997

004

CVD™

GUARDIAN Coronary Dilatation Catheter

Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外枠直径最大限	Model Modello Modèle Modelo Modell モデル
135 cm	3.3F / 2.6F	.014 in	3035

SlyDx™ *featuring advanced coating technology*

STERILE AND NONPYROGENIC

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Steril. Sterilisiert mit Äthylenoxid. Pyrogenfrei. Nur zum einmaligen. Gebrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschädigten. Packungen benutzen. Trocken, dunkel und kühl aufbewahren. Vor Gebrauch Anleitungen durchlesen.

Stérile. Stérilisé à l'oxyde d'éthylène. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'àbri de la lumiére. Lire la notice avant utilisation.

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Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

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13700 Alton Parkway
Irvine, California 92618 USA
(714) 457-9546 • (800) 721-2284
Customer Service (714) 597-8197

6501-0193 Rev A

Developed in conjunction with John McB. Hodgson, MD

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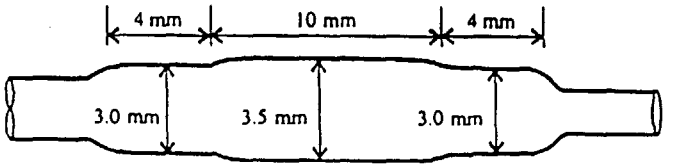

Nominal at 12 Atmospheres

CVD™ GUARDIAN

Rated Burst Pressure	Balloon Diameter		Balloon Length
16 atm	3.0 mm	3.5 mm	18 mm

CVD™ GUARDIAN Coronary Dilatation Catheter

Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外枠直径最大限	Model Modello Modèle Modelo Modell モデル
135 cm	3.3F / 2.6F	.014 in	3040

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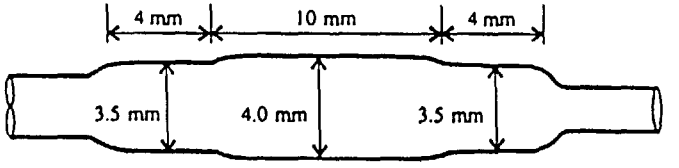

Nominal at 12 Atmospheres

CVD™ GUARDIAN

Rated Burst Pressure 16 atm

Balloon Diameter 3.5 4.0 mm

Balloon Length 18 mm

006

CVD™ GUARDIAN Coronary Dilatation Catheter

Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外枠直径最大限	Model Modello Modèle Modelo Modell モデル
135 cm	3.3F / 2.6F	.014 in	3125

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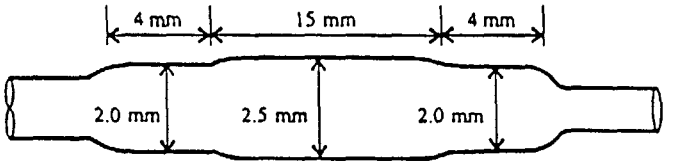

Nominal at 12 Atmospheres

CVD™ GUARDIAN

Rated Burst Pressure 16 atm

Balloon Diameter 2.0 **2.5** mm

Balloon Length 22 mm

CVD™ GUARDIAN Coronary Dilatation Catheter

Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外枠直径最大限	Model Modello Modèle Modelo Modell モデル
135 cm	3.3F / 2.6F	.014 in	3130

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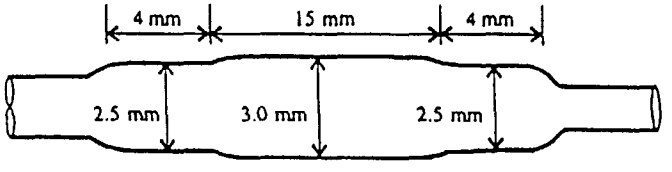

Nominal at 12 Atmospheres

CVD™ GUARDIAN

Rated Burst Pressure	Balloon Diameter		Balloon Length
16 atm	2.5 mm	**3.0**	22 mm

CardioVascular Dynamics, Inc.
PMA Real Time Review of Guardian Coronary Balloon Dilatation Catheter

October 13, 1997

008

CVD™

GUARDIAN Coronary Dilatation Catheter

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135 cm	3.3F / 2.6F	.014 in	3135

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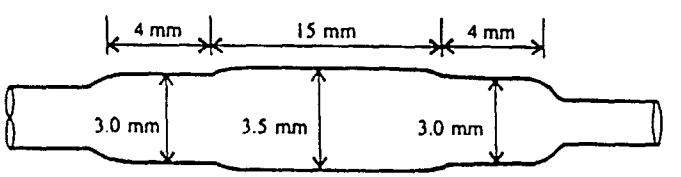

Nominal at 12 Atmospheres

CVD™ GUARDIAN

Rated Burst Pressure 16 atm

Balloon Diameter 3.0 **3.5** mm

Balloon Length 22 mm

009

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135 cm	3.3F / 2.6F	.014 in	3140

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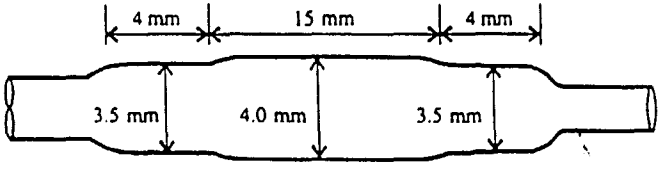


Nominal at 12 Atmospheres

CVD™ GUARDIAN

Rated Burst Pressure	Balloon Diameter		Balloon Length
16 atm	3.5 mm	**4.0** mm	22 mm

010

3.2 DRAFT PACKAGE INSERT

DEVICE NAME: GUARDIAN™ CORONARY BALLOON DILATATION CATHETER

DESCRIPTION

The GUARDIAN™ Coronary Balloon Dilatation Catheter is a double-lumen catheter with a balloon near the distal tip. One lumen is used for inflation of the balloon, and the other lumen permits the use of a coronary guide wire to facilitate the advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an expandable segment of known diameter and length at a specific pressure.

The GUARDIAN™ balloon is formed in a stepped manner so that for the working length of the 18 mm balloon, the center section (10 mm) is formed to the nominal diameter (i.e. 3.5 mm) and the proximal and distal ends of the balloon is stepped down by 0.5 mm (i.e. 3.0 mm).

The nominal diameter of the balloon at 12 atmospheres refers to the center section of the balloon; 10 mm for the 18 mm balloon and a 15 mm center section for the 22 mm balloon.

The catheter is available with a 2.0/2.5 mm balloon, a 2.5/3.0 mm balloon, a 3.0/3.5 mm balloon or a 3.5/4.0 mm balloon. The catheter has a 3.3F proximal shaft and 2.6F for the distal shaft segment. Reference markers are located on the proximal catheter shaft 95 cm and 105 cm from the distal tip for the brachial and femoral approaches, respectively. There are also 2 radiopaque markers at the center section of the balloon.

A two-arm adapter is on the proximal end of the catheter. The sideport of the adapter is connected to the balloon lumen, and has a luer-lock fitting for attaching the catheter to an inflation device. The guide wire port is continuous with the inner lumen of the catheter. The inner lumen allows for free movement of a conventional coronary guide wire equal to or smaller than 0.014 inch.

INDICATIONS

The GUARDIAN™ Coronary Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS

- Unprotected left main coronary artery.
- Coronary artery spasm in the absence of a significant stenosis.

WARNINGS

- This device is intended for one time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA. as treatment of this patient population carries special risks.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the Rated Burst Pressure. The Rated Burst Pressure is based on the results of in-vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their Rated Burst Pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the "Use Before" date specified on the package.
- GUARDIAN™ Balloon Dilatation catheters are not intended for stent expansion.

PRECAUTIONS

- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by physicians trained on the performance of percutaneous transluminal coronary angioplasty.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.
- Carefully review the balloon compliancy data in the Balloon Compliancy Table. Please note balloon diameter versus pressure. The balloon is nominal at 12 atmospheres.

ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, the following:

- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- restenosis of the dilated vessel
- hemorrhage or hematoma
- unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- embolism

INSTRUCTIONS FOR USE

MATERIALS REQUIRED FOR PTCA WITH THE GUARDIAN™ CORONARY BALLOON DILATATION SYSTEM

Quantity	Item Description*
1	0.035 or 0.038 in. x 145 cm guide wire and introducer catheter
1	0.014 in. or smaller x 175 cm guide wire
1	7 to 9F arterial sheath and dilator set (for the femoral approach only)
2 to 3	Femoral or brachial guiding catheters in appropriate size and configuration for the selected coronary artery.
2	Hemostatic side arm adapters
1	Small vial of 60% contrast medium
1	Inflation device for balloon inflation
1 to 2	GUARDIAN™ Coronary Balloon Dilatation Catheter(s). The dilatation catheter is selected according to the severity of the stenosis and the native vessel size. The inflated diameter of the balloon should approximate the coronary artery diameter, and should never exceed the diameter of the coronary artery proximal and distal to the stenosis. In instances of severe stenosis, a smaller balloon may be needed to begin the dilatation process, and it may then be replaced with a larger balloon to effect a successful dilatation.

* These materials are single-use items only.

INSPECTION PRIOR TO USE

Prior to angioplasty, all equipment to be used for the procedures, including the dilatation catheter, should be carefully examined to verify proper performance. It is imperative that the balloon of the dilatation catheter be tested to the maximum pressure to be used during the procedure and that its inflation/deflation time be checked.

PREPARATION OF THE DILATATION CATHETER:

To properly prepare the catheter for use, the following steps should be completed:

1. Filling the inflation device.

    a. Prepare the inflation device according to the manufacturer's instructions.

    b. Purge the system of air. Slide the protective sheath off the balloon.

2. Filling the balloon with contrast solution to displace air.

    a. Prepare a mixture of 50/50% contrast media and sterile saline.

    b. Aspirate 4 cc of contrast mixture into a 20 cc or larger syringe.

    c. Attach the syringe to the balloon leg of the two-arm adapter.

    d. Point the syringe nozzle downward and aspirate for 15 seconds, pulling the plunger all the way back, until no bubbles appear in the syringe.

NOTE: If air bubbles appear in the balloon during purging, do not flick the balloon. Orient the balloon in a downward position and reaspirate. Continue purging until bubbles no longer appear. The use of a 20 cc or larger syringe will facilitate purging.

    e. Infuse the contrast mixture into the balloon, inspecting for leaks or air. Repeat aspiration, if necessary, until air bubbles are no longer present in the syringe during aspiration, or in the balloon during inflation.

    f. Release the positive pressure on the syringe plunger and allow the balloon to resume a neutral state pending connection to the inflation device.

    g. Remove the 20 cc syringe and attach the inflation device to the balloon leg of the two-arm adapter. Be certain the meniscus of contrast solution is evident at the luer fittings to avoid the possible introduction of air. Finger tighten the connections.

PRELIMINARY TESTING OF THE DILATATION CATHETER

1. Prior to the actual use, the dilatation catheter should be tested by inflating the balloon to the Rated Burst Pressure (see Table 7.1). The time required to fully inflate and deflate the balloon should be checked.

2. Verify that the three-way stopcock connected to the inflation device and dilatation catheter is open. Inflate the balloon to the nominal inflation pressure (see Table 7.1), and sustain that pressure for five seconds. The balloon should appear fully inflated within ten seconds of pressurization. Retract the plunger to fully deflate the balloon. It should appear fully deflated within twenty-five seconds after applying negative pressure. Repeat the inflations and deflations for three cycles, and record the times. Retract the plunger to fully deflate the balloon, then close the three-way stopcock connected to the inflation device and dilatation catheter. Insert the balloon into the protective sheath, reopen the three-way stopcock and set it aside until ready for use. Do not allow negative pressure to remain on the balloon catheter.

PROCEDURE TECHNIQUE:

1. To insert the catheter:

   a. Prepare and drape the selected entry site.

   b. Administer local anesthetic.

      NOTE: If using the brachial approach, disregard substeps (c) through (i). Perform confirmatory arteriography, including intravenous heparin administration using conventional catheterization techniques. Replace the angiographic catheters with an appropriate Brachial Guiding Catheter using an 0.035 in. or 0.038 in. x 145 cm guide wire. Continue with Step 2.

   c. Cannulate the femoral artery with an appropriate percutaneous needle. Remove the obturator to confirm that the needle is within the lumen of the artery.

   d. Introduce a 0.035 inch or 0.038 inch x 145 cm guide wire, flexible end first, through the needle and into the vessel. Advance the distal tip of the guide wire to the level of the diaphragm under fluoroscopy. Insert a standard angiographic catheter over the guide wire, and advance it to the arch of the aorta.

      NOTE: Never advance a guide wire if resistance is encountered without first determining the cause of resistance by fluoroscopy.

e. Anticoagulate the patient with intravenous heparin. Perform baseline coronary arteriography to confirm the severity of the stenosis and to verify that the patient still meets the indication criteria for PTCA.

f. Flush the guiding catheter.

g. Using standard percutaneous techniques, replace the angiographic catheter with a 7F to 9F sheath. Insert the guiding catheter through the sheath over a guide wire. Advance it to the descending aorta under fluoroscopy.

h. Continue advancing the guiding catheter to the ascending aorta under fluoroscopy. The guide wire and introducer should precede the tip of the guiding catheter until its tip is around the aortic arch.

i. Start withdrawing the guide wire as the guiding catheter is advanced into position. Remove the guide wire.

2. Attach a coronary manifold to the side arm of the hemostatic side-arm adapter with a short connecting tubing. Flush the device with normal saline to eliminate any air. To properly flush the valve arm, use a thumb or finger to cap the fitting that connects the arm to the guiding catheter. Open the valve, and flush saline through the device. Close the valve and connect the hemostatic side-arm adapter to the guiding catheter.

3. Join a second hemostatic valve to a coronary manifold with connecting tubing. Flush and fill as in Step 2.

a. Connect the hemostatic valve to the guide wire port of the two-arm adapter of the dilatation catheter. Flush and fill the guide wire lumen of the dilatation catheter with heparinized normal saline.

b. Loosen the knurled knob of the hemostatic valve and open the saline stopcock on the manifold so that fluid drips from the hemostatic valve.

c. Insert a guide wire introducer through the hemostatic valve to facilitate introduction of the guide wire into the dilatation catheter. Advance the guide wire carefully into and through the lumen of the dilatation catheter. Position the tip of the guide wire so that it is just inside the tip of the dilatation catheter.

d. Withdraw the guide wire introducer and tighten the knurled knob so that the valve closes firmly around the guide wire. Close the saline stopcock on the manifold.

4. Aspirate the guiding catheter to free any trapped air. Flush the guiding catheter with normal saline, fill it with contrast medium, and selectively engage it in the appropriate coronary ostium. Confirm the catheter position by arteriography.

5. Remove the balloon sheath.

NOTE: All air must be removed from the GUARDIAN™ catheter and displaced with heparinized saline prior to inserting it into the body. Otherwise complications may occur.

6. Loosen the knurled screw fitting on the hemostatic side-arm adapter which is attached to the guiding catheter so that it is possible to pass the dilatation catheter through the valve. Then introduce the dilatation catheter into the guiding catheter. It is imperative that the balloon be fully deflated during this process.

7. Re-tighten the fitting, after the dilatation catheter has been inserted at least 30 to 40 cm into the guiding catheter, to create a seal around the dilatation catheter that does not inhibit movement of the catheter. This will allow continuous recording of proximal coronary artery pressure. Advance the dilatation catheter and guidewire to the tip of the guiding catheter. Proximal markers located approximately 95 and 105 centimeters from the distal tip aid in identifying how far the dilatation catheter is advanced in brachial and femoral guiding catheters, respectively. When the marker is aligned with the hemostatic valve hub, the dilatation catheter tip has reached the guiding catheter tip (i.e., when using a brachial guiding catheter, use the 95 centimeters marker as a gauge and when using a femoral guiding catheters, use the 105 centimeters marker as a gauge).

NOTE: It is important that the valve be closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon.

Attach the torque device to the guidewire. Keep the valve of the guidewire hemostatic side-arm adapter appropriately closed when the guidewire is in the catheter. When the valve is appropriately closed, intentional movement of the wire is not inhibited.

8. Advance the guidewire, under fluoroscopy, out of the tip of the guiding catheter and select the desired coronary artery. Continue advancing the guidewire to and then across the stenosis while frequently confirming its position with contrast injections through the guiding catheter. The GUARDIAN™ catheter may be incrementally advanced following the guidewire to provide additional support to the guidewire as it negotiates the coronary artery and crosses the stenosis. The spring tip of the guidewire may be rotated to facilitate the processes of vessel negotiation and crossing the stenosis by slowly turning the torque device.

9. Hold the guidewire stationary and advance the GUARDIAN™ catheter over the guidewire and into the stenosis. The radiopaque balloon markers and a very low pressure (10 to 20 psi) balloon inflation should be used to confirm that the indentation caused by the stenosis is centrally located within the balloon segment before proceeding with the dilatation.

10. Inflate the balloon to perform PTCA per standard procedure. Deflate the balloon. Maintain negative pressure on the balloon between dilatations by pulling negative pressure, then closing the inflation device stopcock.

11. After the first inflation and each subsequent inflation, assess distal coronary blood flow by arteriography through the guiding catheter while the deflated balloon remains in the stenosis. Maintain the guidewire across the stenosis until distal blood flow is adequate. If distal coronary blood flow is reduced and myocardial ischemia develops before an effective dilatation is achieved, the guidewire may be advanced and maintained across the stenosis as the balloon is withdrawn, permitting reperfusion of the distal vessel.

12. Prior to removing the balloon, check the balloon to verify that it is fully deflated and then close the stopcock of the inflation device to maintain the vacuum. With the balloon deflated, simultaneously withdraw the dilatation catheter and guidewire out of the coronary artery and into the lumen of the guiding catheter. Remove the dilatation catheter from the guiding catheter through the hemostatic side-arm adapter. Close the valve of the hemostatic side-arm adapter.

NOTE: The guiding catheter is not recommended for routine arteriography. A standard coronary angiographic catheter should be used for post-angioplasty arteriography.

13. Carefully remove the guiding catheter, then follow standard practice for management of the insertion site.

BALLOON COMPLIANCE TABLE

INFLATION PRESSURE (ATMS)	2.0/2.5 mm Balloon Diameter			2.5/3.0 mm Balloon Diameter			3.0/3.5 mm Balloon Diameter			3.5/4.0 mm Balloon Diameter		
	Prox	Center	Distal	Prox	Center	Distal	Prox	Center	Distal	Prox	Center	Distal
2	1.9	2.4	1.9	2.4	2.9	2.4	2.8	3.4	2.8	3.3	3.8	3.3
3	1.9	2.4	1.9	2.4	2.9	2.4	2.8	3.4	2.8	3.4	3.8	3.4
4	1.9	2.4	1.9	2.4	2.9	2.4	2.9	3.4	2.9	3.4	3.9	3.4
5	2.0	2.4	2.0	2.4	2.9	2.4	2.9	3.5	2.9	3.4	3.9	3.4
6	2.0	2.4	2.0	2.4	3.0	2.4	2.9	3.5	2.9	3.4	3.9	3.4
7	2.0	2.4	2.0	2.4	3.0	2.4	2.9	3.5	2.9	3.4	3.9	3.4
8	2.0	2.5	2.0	2.5	3.0	2.5	2.9	3.5	2.9	3.4	3.9	3.4
9	2.0	2.5	2.0	2.5	3.0	2.5	2.9	3.5	2.9	3.5	3.9	3.5
10	2.0	2.5	2.0	2.5	3.0	2.5	3.0	3.5	3.0	3.5	3.9	3.5
11	2.0	2.5	2.0	2.5	3.0	2.5	3.0	3.5	3.0	3.5	4.0	3.5
12	2.0	2.5	2.0	2.5	3.0	2.5	3.0	3.5	3.0	3.5	4.0	3.5
13	2.0	2.5	2.0	2.5	3.0	2.5	3.0	3.5	3.0	3.5	4.0	3.5
14	2.0	2.5	2.0	2.6	3.1	2.6	3.0	3.6	3.0	3.5	4.0	3.5
15	2.1	2.5	2.1	2.6	3.1	2.6	3.0	3.6	3.0	3.5	4.0	3.5
16	2.1	2.5	2.1	2.6	3.1	2.6	3.0	3.6	3.0	3.6	4.0	3.6
17	2.1	2.5	2.1	2.6	3.1	2.6	3.1	3.6	3.1	3.6	4.1	3.6
18	2.1	2.5	2.1	2.6	3.2	2.6	3.1	3.6	3.1	3.6	4.1	3.6
19	2.1	2.5	2.1	2.6	3.2	2.6	3.2	3.6	3.2	3.6	4.2	3.6
20	2.1	2.5	2.1	2.7	3.2	2.7	3.2	3.7	3.2	3.7	4.2	3.7

Nominal Inflation Pressure

Rated Burst Pressure

REPACKAGING INSTRUCTIONS:

In the event the catheter must be returned for any reason, return the GUARDIAN™ catheter in its original package and shipping box. Contact CardioVascular Dynamics to receive a Return Authorization Number prior to return shipment.

REFERENCES

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by ACC/AHA.

WARRANTY AND LIMITATIONS

CardioVascular Dynamics has exercised reasonable care in the manufacture of the GUARDIAN™ catheter. CardioVascular Dynamics warrants that the GUARDIAN™ catheters shall be free of defects in materials and workmanship upon receipt. CardioVascular Dynamics warranty shall not apply to these products of they have been altered or utilized in a manner not approved by CardioVascular Dynamics or subjected to misuse, negligence or accident. The liabilities of CardioVascular Dynamics arising out of supplying this product whether based on warranty or otherwise, shall in no case exceed the price of this product.

CardioVascular Dynamics makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the re-use of this catheter.

In addition, CardioVascular Dynamics assumes no responsibility or liability for incidental or consequential damages which may result from such re-use.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:

CardioVascular Dynamics, Inc.
137900 Alton Parkway
Irvine, CA 92618
(714) 457-9546 • (800) 721-2284

October 1997

CVD™ LYNX™ CONTOUR™ CORONARY DILATATION CATHETER

STERILE AND NONPYROGENIC

Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For one procedure only. Do not resterilize. Do not use open or damaged packages. Store in a dry, dark, cool place. Refer to accompanying Instructions for Use.

Steril.Sterilisiert mit Athylenoxid. Pyrogenfrei. Nur zum einmaligen. Gerbrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschadigten. Packungen benutzen. Trocken, dunkel und kuhl aufbewahren. Vor Gebrauch Anleitungen durchlesen.

Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'àbri de la lumiére. Lire la notice avant utilisation.

Estéril. Esterilizado con óxido de etileno. Apirógeno. Para un solo uso. No reesterilizar. No utilizar si el embalaje está abierto o deteriorado. Almacenar en un lugar fresco, uscuro y seco. Leer las instrucciones antes de usar.

Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

殺菌　エチレン酸化ガスで殺菌．不加熱．一手段のみ．再殺菌をしないでください．開封または破れたパッケージは使用しないでください．乾燥した冷暗所に保存してください．使用につきましては、説明書を参考にしてください．

CAUTION

Federal (USA) law restricts this device to sale, distribution and use by or under order of a physician.

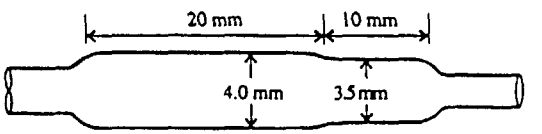
CONTENTS

Contents: Inhalt: Contenu: Contenido: Contenuto: 内容物:　1

Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外枠直径最大限
135 cm	3.5F / 2.9F	.014 in

featuring SlyDx™ *advanced coating technology*

CARDIOVASCULAR DYNAMICS, INC.
13900 Alton Parkway, Suite 122
Irvine, California 92618
714-457-9546 • FAX 714-457-9561
Customer Service 800-721-2284



Nominal at 12 atmospheres

650-00321 Rev 1

Manufactured under one or more of the following patents:
5,295,962; 5,344,402; 5,368,566; 5,421,826; 5,470,313; 5,522,800
U.S. and foreign patents pending

CVD™ LYNX™ CONTOUR™ 16 atm Rated Burst

Balloon Diameter / Ballondurchmesser / Diamètre du ballon / Diámetro del balón / Ø del Palloncino / 風船の直径: 3.5 **4.0** mm

Balloon Length / Ballonlänge / Long du ballon / Long del balón / Long del palloncino / 風船の長さ: 30 mm

13040 Model

SECTION VII.B. DRAFT PACKAGE INSERT

I. DEVICE NAME: CONTOUR™ BALLOON DILATATION CATHETER

II. DESCRIPTION

The CONTOUR™ Coronary Balloon Dilatation Catheter is a double-lumen catheter with a balloon near the distal tip. One lumen is used for inflation of the balloon, and the other lumen permits the use of a coronary guidewire to facilitate the advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an expandable segment of known diameter and length at a specific pressure.

The CONTOUR™ balloon is formed in a stepped manner so that for the working length of the 30 mm balloon, the proximal section (20 mm) is formed to the nominal diameter (i.e. 3.5 mm) and the distal end of the balloon is stepped down by 0.5 mm (i.e. 3.0 mm).

The nominal diameter of the balloon at 12 atmospheres refers to the proximal section of the balloon; 20 mm for the 30 mm balloon and a 30 mm proximal section for the 40 mm balloon.

The catheter is available with a 2.0/2.5 mm balloon, a 2.5/3.0 mm balloon, a 3.0/3.5 mm balloon or a 3.5/4.0 mm balloon. The catheter has a 3.5F proximal shaft and 2.9F for the distal shaft segment. Reference markers are located on the proximal catheter shaft 95 cm and 105 cm from the distal tip for the brachial and femoral approaches, respectively. There is a radiopaque marker at the center of the step from the proximal to the distal sections of the balloon.

A two-arm adapter is on the proximal end of the catheter. The sideport of the adapter is connected to the balloon lumen, and has a luer-lock fitting for attaching the catheter to an inflation device. The guidewire port is continuous with the inner lumen of the catheter. The inner lumen allows for free movement of a conventional coronary guidewire equal to or smaller than 0.014 inch.

III. INDICATIONS

The CONTOUR™ Coronary Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

IV. CONTRAINDICATIONS

- Unprotected left main coronary artery.

- Coronary artery spasm in the absence of a significant stenosis.

V. WARNINGS

- This device is intended for one time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.

- To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risks.

- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

- Balloon pressure should not exceed the Rated Burst Pressure. The Rated Burst Pressure is based on the results of in-vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their Rated Burst Pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.

- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

- Use the catheter prior to the expiration date specified on the package.

- CONTOUR™ Balloon Dilatation catheters are not intended for stent expansion.

VI. PRECAUTIONS

- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

- The catheter system should be used only by physicians trained on the performance of percutaneous transluminal coronary angioplasty.

- During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

- Carefully review the balloon compliancy data in Table I. Please note balloon diameter versus pressure. The balloon is nominal at 12 atmospheres.

VII. ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, the following:

- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury

- restenosis of the dilated vessel
- hemorrhage or hematoma
- unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- embolism

VIII. INSTRUCTIONS FOR USE

MATERIALS REQUIRED FOR PTCA WITH THE CONTOUR™ BALLOON DILATATION SYSTEM

Quantity	Item Description*
1	0.035 or 0.038 in. x 145 cm guidewire and introducer catheter
1	0.014 in. or smaller x 175 cm guidewire
1	6 to 9F arterial sheath and dilator set (for the femoral approach only)
2 to 3	Femoral or brachial guiding catheters in appropriate size and configuration for the selected coronary artery.
2	Hemostatic side arm adapters
1	Small vial of 60% contrast medium
1	Inflation device for balloon inflation
1 to 2	CONTOUR™ Coronary Balloon Dilatation Catheter(s). The dilatation catheter is selected according to the severity of the stenosis and the native vessel size. The inflated diameter of the balloon should approximate the coronary artery diameter, and should never exceed the diameter of the coronary artery proximal and distal to the stenosis. In instances of severe stenosis, a smaller balloon

may be needed to begin the dilatation process, and it may then be replaced with a larger balloon to effect a successful dilatation.

* These materials are single-use items only.

INSPECTION PRIOR TO USE

Prior to angioplasty, all equipment to be used for the procedures, including the dilatation catheter, should be carefully examined to verify proper performance. It is imperative that the balloon of the dilatation catheter be tested to the maximum pressure to be used during the procedure and that its inflation/deflation time be checked.

PREPARATION OF THE DILATATION CATHETER:

To properly prepare the catheter for use, the following steps should be completed:

1. Filling the inflation device.

    a. Prepare the inflation device according to the manufacturer's instructions.

    b. Purge the system of air. Slide the protective sheath off the balloon.

2. Filling the balloon with contrast solution to displace air.

    a. Prepare a mixture of 50/50% contrast media and sterile saline.

    b. Aspirate 4 cc of contrast mixture into a 20 cc or larger syringe.

    c. Attach the syringe to the balloon leg of the two-arm adapter.

    d. Point the syringe nozzle downward and aspirate for 15 seconds, pulling the plunger all the way back, until no bubbles appear in the syringe.

NOTE: If air bubbles appear in the balloon during purging, do not flick the balloon. Orient the balloon in a downward position and reaspirate. Continue purging until bubbles no longer appear. The use of a 20 cc or larger syringe will facilitate purging.

    e. Infuse the contrast mixture into the balloon, inspecting for leaks or air. Repeat aspiration, if necessary, until air bubbles are no longer present

in the syringe during aspiration, or in the balloon during inflation.

f. Release the positive pressure on the syringe plunger and allow the balloon to resume a neutral state pending connection to the inflation device.

g. Remove the 20 cc syringe and attach the inflation device to the balloon leg of the two-arm adapter. Be certain the meniscus of contrast solution is evident at the luer fittings to avoid the possible introduction of air. Finger tighten the connections.

PRELIMINARY TESTING OF THE DILATATION CATHETER

1. Prior to the actual use, the dilatation catheter should be tested by inflating the balloon to the Rated Burst Pressure (see Table 7.1). The time required to fully inflate and deflate the balloon should be checked.

2. Verify that the three-way stopcock connected to the inflation device and dilatation catheter is open. Inflate the balloon to the nominal inflation pressure (see Table 7.1), and sustain that pressure for five seconds. The balloon should appear fully inflated within ten seconds of pressurization. Retract the plunger to fully deflate the balloon. It should appear fully deflated within twenty-five seconds after applying negative pressure. Repeat the inflations and deflations for three cycles, and record the times. Retract the plunger to fully deflate the balloon, then close the three-way stopcock connected to the inflation device and dilatation catheter. Insert the balloon into the protective sheath, reopen the three-way stopcock and set it aside until ready for use. Do not allow negative pressure to remain on the balloon catheter.

PROCEDURE TECHNIQUE:

1. To insert the catheter:

   a. Prepare and drape the selected entry site.

   b. Administer local anesthetic.

NOTE: If using the brachial approach, disregard substeps (c) through (i). Perform confirmatory arteriography, including intravenous heparin administration using conventional catheterization techniques. Replace the angiographic catheters with an appropriate Brachial Guiding Catheter using an 0.035 in. or 0.038 in. x 145 cm guidewire. Continue with Step 2.

c. Cannulate the femoral artery with an appropriate percutaneous needle. Remove the obturator to confirm that the needle is within the lumen of the artery.

d. Introduce a 0.035 inch or 0.038 inch x 145 cm guidewire, flexible end first, through the needle and into the vessel. Advance the distal tip of the guidewire to the level of the diaphragm under fluoroscopy. Insert a standard angiographic catheter over the guidewire, and advance it to the arch of the aorta.

NOTE: Never advance a guidewire if resistance is encountered without first determining the cause of resistance by fluoroscopy.

e. Anticoagulate the patient with intravenous heparin. Perform baseline coronary arteriography to confirm the severity of the stenosis and to verify that the patient still meets the indication criteria for PTCA.

f. Flush the guiding catheter.

g. Using standard percutaneous techniques, replace the angiographic catheter with a 6F to 9F sheath. Insert the guiding catheter through the sheath over a guidewire. Advance it to the descending aorta under fluoroscopy.

h. Continue advancing the guiding catheter to the ascending aorta under fluoroscopy. The guidewire and introducer should precede the tip of the guiding catheter until its tip is around the aortic arch.

i. Start withdrawing the guidewire as the guiding catheter is advanced into position. Remove the guidewire.

2. Attach a coronary manifold to the side arm of the hemostatic side-arm adapter with a short connecting tubing. Flush the device with normal saline to eliminate any air. To properly flush the valve arm, use a thumb or finger to cap the fitting that connects the arm to the guiding catheter. Open the valve, and flush saline through the device. Close the valve and connect the hemostatic side-arm adapter to the guiding catheter.

3. Join a second hemostatic valve to a coronary manifold with connecting tubing. Flush and fill as in Step 2.

   a. Connect the hemostatic valve to the guidewire port of the two-arm adapter of the dilatation catheter. Flush and fill the guidewire lumen of the dilatation catheter with heparinized normal saline.

   b. Loosen the knurled knob of the hemostatic valve and open the saline stopcock on the manifold so that fluid drips from the hemostatic valve.

   c. Insert a guidewire introducer through the hemostatic valve to facilitate introduction of the guidewire into the dilatation catheter. Advance the guidewire carefully into and through the lumen of the dilatation catheter. Position the tip of the guidewire so that it is just inside the tip of the dilatation catheter.

   d. Withdraw the guidewire introducer and tighten the knurled knob so that the valve closes firmly around the guidewire. Close the saline stopcock on the manifold.

4. Aspirate the guiding catheter to free any trapped air. Flush the guiding catheter with normal saline, fill it with contrast medium, and selectively engage it in the appropriate coronary ostium. Confirm the catheter position by arteriography.

5. Remove the balloon sheath.

NOTE: All air must be removed from the CONTOUR™ catheter and displaced with heparinized saline prior to inserting it into the body. Otherwise complications may occur.

6. Loosen the knurled screw fitting on the hemostatic side-arm adapter which is attached to the guiding catheter so that it is possible to pass the dilatation catheter through the valve. Then introduce the dilatation catheter into the guiding catheter. It is imperative that the balloon be fully deflated during this process.

7. Re-tighten the fitting, after the dilatation catheter has been inserted at least 30 to 40 cm into the guiding catheter, to create a seal around the dilatation catheter that does not inhibit movement of the catheter. This will allow continuous recording of proximal coronary artery pressure. Advance the dilatation catheter and guidewire to the tip of the guiding catheter. Proximal markers located approximately 95 and 105 centimeters from the distal tip aid in identifying how far the dilatation catheter is advanced in brachial and femoral guiding catheters, respectively. When the marker is aligned with the hemostatic valve hub, the dilatation catheter tip has reached the guiding catheter tip (i.e., when using a brachial guiding catheter, use the 95 centimeters marker as a gauge and when using a femoral guiding catheters, use the 105 centimeters marker as a gauge).

NOTE: It is important that the valve be closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon.

Attach the torque device to the guidewire. Keep the valve of the guidewire hemostatic side-arm adapter appropriately closed when the guidewire is in the catheter. When the valve is appropriately closed, intentional movement of the wire is not inhibited.

8. Advance the guidewire, under fluoroscopy, out of the tip of the guiding catheter and select the desired coronary artery. Continue advancing the guidewire to and then across the stenosis while frequently confirming its position with contrast injections through the guiding catheter. The CONTOUR™ catheter may be incrementally advanced following the guidewire to provide additional support to the guidewire as it negotiates the coronary artery and crosses the stenosis. The spring tip of the guidewire may be rotated to facilitate the processes of vessel negotiation and crossing the stenosis by slowly turning the torque device.

9. Hold the guidewire stationary and advance the CONTOUR™ catheter over the guidewire and into the stenosis. The radiopaque balloon marker and a very low pressure (10 to 20 psi) balloon inflation should be used to confirm that the indentation caused by the stenosis is centrally located within the balloon segment before proceeding with the dilatation.

10. Inflate the balloon to perform PTCA per standard procedure. Deflate the balloon. Maintain negative pressure on the balloon between dilatations by pulling negative pressure, then closing the inflation device stopcock.

11. After the first inflation and each subsequent inflation, assess distal coronary blood flow by arteriography through the guiding catheter while the deflated balloon remains in the stenosis. Maintain the guidewire across the stenosis until distal blood flow is adequate. If distal coronary blood flow is reduced and myocardial ischemia develops before an effective dilatation is achieved, the guidewire may be advanced and maintained across the stenosis as the balloon is withdrawn, permitting reperfusion of the distal vessel.

12. Prior to removing the balloon, check the balloon to verify that it is fully deflated and then close the stopcock of the inflation device to maintain the vacuum. With the balloon deflated, simultaneously withdraw the dilatation catheter and guidewire out of the coronary artery and into the lumen of the

guiding catheter. Remove the dilatation catheter from the guiding catheter through the hemostatic side-arm adapter. Close the valve of the hemostatic side-arm adapter.

NOTE: The guiding catheter is not recommended for routine arteriography. A standard coronary angiographic catheter should be used for post-angioplasty arteriography.

13. Carefully remove the guiding catheter, then follow standard practice for management of the insertion site.

TABLE 7.1

BALLOON COMPLIANCE

INFLATION PRESSURE (ATMS	2.0/2.5 mm Balloon Diameter 30 mm		2.5/3.0 mm Balloon Diameter 30 mm		3.0/3.5 mm Balloon Diameter 30 mm		3.5/4.0 mm Balloon Diameter 30 mm		3.5/4.0 mm Balloon Diameter 40 mm		
	Prox	Distal	Prox	Distal	Prox	Distal	Prox	Distal	Prox	Distal	
2	2.3	1.9	2.8	2.3	3.4	2.9	3.7	3.3	3.7	3.3	
3	2.4	1.9	2.8	2.3	3.4	2.9	3.8	3.3	3.8	3.3	
4	2.4	1.9	2.9	2.4	3.4	2.9	3.8	3.3	3.8	3.3	
5	2.4	1.9	2.9	2.4	3.4	2.9	3.8	3.3	3.8	3.3	
6	2.4	1.9	2.9	2.4	3.4	2.9	3.8	3.3	3.8	3.3	
7	2.4	1.9	2.9	2.4	3.5	2.9	3.9	3.4	3.9	3.4	
8	2.4	1.9	3.0	2.4	3.5	3.0	3.9	3.4	3.9	3.4	
9	2.4	1.9	3.0	2.4	3.5	3.0	3.9	3.4	3.9	3.4	
10	2.5	2.0	3.0	2.4	3.5	3.0	4.0	3.4	3.9	3.4	
11	2.5	2.0	3.0	2.4	3.5	3.0	4.0	3.4	4.0	3.4	
12	**2.5**	**2.0**	**3.0**	**2.5**	**3.5**	**3.0**	**4.0**	**3.4**	**4.0**	**3.4**	Nominal Inflation Pressure
13	2.5	2.0	3.0	2.5	3.5	3.0	4.0	3.5	4.0	3.4	
14	2.5	2.0	3.0	2.5	3.5	3.0	4.0	3.5	4.0	3.4	
15	2.5	2.0	3.0	2.5	3.6	3.0	4.0	3.5	4.0	3.5	
16	**2.5**	**2.0**	**3.0**	**2.5**	**3.6**	**3.0**	**4.1**	**3.5**	**4.0**	**3.5**	Rated Burst Pressure
17	2.5	2.0	3.1	2.5	3.6	3.1	4.1	3.5	4.1	3.5	
18	2.5	2.0	3.1	2.5	3.6	3.1	4.1	3.6	4.1	3.5	
19	2.5	2.0	3.1	2.6	3.6	3.1	4.1	3.6	4.1	3.5	
20	2.6	2.0	3.1	2.6	3.7	3.1	4.2	3.6	4.1	3.5	

REPACKAGING INSTRUCTIONS:

In the event the catheter must be returned for any reason, return the CONTOUR™ catheter in its original package and shipping box. Contact CardioVascular Dynamics to receive a Return Authorization Number prior to return shipment.

IX. REFERENCES

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by ACC/AHA.

X. WARRANTY AND LIMITATIONS

CardioVascular Dynamics has exercised reasonable care in the manufacture of the CONTOUR™ catheter. CardioVascular Dynamics warrants that the CONTOUR™ catheters shall be free of defects in materials and workmanship upon receipt. CardioVascular Dynamics warranty shall not apply to these products of they have been altered or utilized in a manner not approved by CardioVascular Dynamics or subjected to misuse, negligence or accident. The liabilities of CardioVascular Dynamics arising out of supplying this product whether based on warranty or otherwise, shall in no case exceed the price of this product.

CardioVascular Dynamics makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the re-use of this catheter.

In addition, CardioVascular Dynamics assumes no responsibility or liability for incidental or consequential damages which may result from such re-use.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:

CardioVascular Dynamics, Inc.
13700 Alton Parkway
Irvine, CA 92618
(714) 457-9546 • (800) 721-2284

650-0195
2/28/97

CVD™ FACT™ CORONARY DILATATION CATHETER

STERILE AND NONPYROGENIC

Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For one procedure only. Do not resterilize. Do not use open or damaged packages. Store in a dry, dark, cool place. Refer to accompanying Instructions for Use.

Steril. Sterilisiert mit Athylenoxid. Pyrogenfrei. Nur zum einmaligen. Gerbrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschadigten. Packungen benutzen. Trocken, dunkel und kuhl aufbewahren. Vor Gebrauch Anleitungen durchlesen.

Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'àbri de la lumiére. Lire la notice avant utilisation.

Estéril. Esterilizado con óxido de etileno. Apirógeno. Para un solo uso. No reesterilizar. No utilizar si el embalaje está abierto o deteriorado. Almacenar en un lugar fresco, oscuro y seco. Leer las instrucciones antes du su uso.

Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

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135 cm	**3.5F / 3.0F**	**.014 in**

featuring SlyDx™ *advanced coating technology*

DRAFT LABELING

CVD™ CARDIOVASCULAR DYNAMICS, INC.
13900 Alton Parkway, Suite 122
Irvine, California 92618
714-457-9546 • FAX 714-457-9561
Customer Service 800-721-2284

650-0241 Rev. 1

Manufactured under one or more of the following patents:
5,295,962; 5,344,402; 5,368,566; 5,421,826; 5,470,313
U.S. and foreign patents pending

CVD™ FACT™

12 atm
Rated Burst

Balloon Diameter
Ballondurchmesser
Diamètre du ballon
Diámetro del balón
Ø del Palloncino
風船の直径
4.0 mm

Balloon Length
Ballonlänge
Long du ballon
Long del balón
Lung del palloncino
風船の長さ
20 mm

6440
Model

CVD™ FACT™ CORONARY DILATATION CATHETER

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Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'ábri de la lumiére. Lire la notice avant utilisation.

Estéril. Esterilizado con óxido de etileno. Apirógeno. Para un solo uso. No reesterilizar. No utilizar si el embalaje está abierto o deteriorado. Almacenar en un lugar fresco, oscuro y seco. Leer las instrucciones antes du su uso.

Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

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135 cm	**3.5F / 3.0F**	**.014 in**

featuring SlyDx™ *advanced coating technology*

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Customer Service 800-721-2284

650-0240 Rev. 1

CVD™ FACT™

12 atm
Rated Burst

Balloon Diameter
Ballondurchmesser
Diamètre du ballon
Diámetro del balón
Ø del Palloncino
風船の直径
3.5 mm

Balloon Length
Ballonlänge
Long du ballon
Long del balón
Lung del palloncino
風船の長さ
20 mm

6435
Model

FACT™ Coronary Balloon Dilatation Catheter
ARC™ Coronary Balloon Dilatation Catheter
July 20, 1996

DRAFT LABELING

0622

CVD™ FACT™ CORONARY DILATATION CATHETER

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殺菌　エチレン酸化ガスで殺菌。不加熱。　一手段のみ。再殺菌をしないでください。開封または破れたパッケージは使用しないでください。乾燥した冷暗所に保存してください。使用につきましては、説明書を参考にしてください。

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135 cm	**3.5F / 3.0F**	**.014 in**

featuring SlyDx™ *advanced coating technology*

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FACT™ Coronary Balloon Dilatation Catheter
ARC™ Coronary Balloon Dilatation Catheter
July 20, 1996

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714-457-9546 • FAX 714-457-9561
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650-0238 Rev. 1

Manufactured under one or more of the following patents:
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U.S. and foreign patents pending

CVD™ FACT™

12 atm
Rated Burst

Balloon Diameter
Ballondurchmesser
Diamètre du ballon
Diámetro del balón
Ø del Palloncino
風船の直径
2.5 mm

Balloon Length
Ballonlänge
Long du ballon
Long del balón
Lung del palloncino
風船の長さ
20 mm

6425
Model

0641 87

Draft

PACKAGE INSERT

I. DEVICE NAME: FACT™ CORONARY BALLOON DILATATION CATHETER

II. DESCRIPTION

The FACT™ Coronary Balloon Dilatation Catheter is a double-lumen catheter with a balloon near the distal tip. One lumen is used for inflation of the balloon, and the other lumen permits the use of a coronary guide wire to facilitate the advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an expandable segment of known diameter and length at a specific pressure.

The catheter is available with a 2.5 mm balloon, a 3.0 mm balloon, a 3.5 mm balloon or a 4.0 mm balloon. The catheter has a 3.5F proximal shaft and 3.0F for the distal shaft segment. Reference markers are located on the proximal catheter shaft 95 cm and 105 cm from the distal tip for the brachial and femoral approaches, respectively. There are also radiopaque markers at the center section of the balloon.

A two-arm adapter is on the proximal end of the catheter. The sideport of the adapter is connected to the balloon lumen, and has a luer-lock fitting for attaching the catheter to an inflation device. The guide wire port is continuous with the inner lumen of the catheter. The inner lumen allows for free movement of a conventional coronary guide wire equal to or smaller than 0.014 inch.

III. INDICATIONS

The FACT™ Coronary Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

IV. CONTRAINDICATIONS

- Unprotected left main coronary artery.
- Coronary artery spasm in the absence of a significant stenosis.

V. WARNINGS

- This device is intended for one time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.

- To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA. as treatment of this patient population carries special risks.

- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

- Balloon pressure should not exceed the Rated Burst Pressure. The Rated Burst Pressure is based on the results of in-vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their Rated Burst Pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.

- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

- Use the catheter prior to the "Use Before" date specified on the package.

VI. PRECAUTIONS

- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by physicians trained on the performance of percutaneous transluminal coronary angioplasty.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.
- Carefully review the balloon compliancy data in Table I. Please note balloon diameter versus pressure. The balloon is nominal at 6 atmospheres. When the balloon is inflated to 11 atmospheres, the balloon has reached the next 0.5 mm in size.

VII. ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, the following:

- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- restenosis of the dilated vessel
- hemorrhage or hematoma
- unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- embolism

VIII. INSTRUCTIONS FOR USE

MATERIALS REQUIRED FOR PTCA WITH THE FACT™ CORONARY BALLOON DILATATION SYSTEM

Quantity	Item Description*
1	0.035 or 0.038 in. x 145 cm guide wire and introducer catheter
1	0.014 in. or smaller x 175 cm guide wire
1	7 to 9F arterial sheath and dilator set (for the femoral approach only)
2 to 3	Femoral or brachial guiding catheters in appropriate size and configuration for the selected coronary artery.
2	Hemostatic side arm adapters
1	Small vial of 60% contrast medium
1	Inflation device for balloon inflation
1 to 2	FACT™ Coronary Balloon Dilatation Catheter(s). (The dilatation catheter is selected according to the severity of the stenosis and the native vessel size. The inflated diameter of the balloon should approximate the coronary artery diameter, and should never exceed the diameter of the coronary artery proximal and distal to the stenosis. In instances of severe stenosis, a smaller balloon may be needed to begin the dilatation process, and it may then be replaced with a larger balloon to effect a successful dilatation.)

* These materials are single-use items only.

INSPECTION PRIOR TO USE

Prior to angioplasty, all equipment to be used for the procedures, including the dilatation catheter, should be carefully examined to verify proper performance. It is imperative that the balloon of the dilatation catheter be tested to the maximum pressure to be used during the procedure and that its inflation/deflation time be checked.

PREPARATION OF THE DILATATION CATHETER:

To properly prepare the catheter for use, the following steps should be completed:

1. Filling the inflation device.

    a. Prepare the inflation device according to the manufacturer's instructions.

    b. Purge the system of air. Slide the protective sheath off the balloon.

2. Filling the balloon with contrast solution to displace air.

    a. Prepare a mixture of 50/50% contrast media and sterile saline.

    b. Aspirate 4 cc of contrast mixture into a 20 cc or larger syringe.

    c. Attach the syringe to the balloon leg of the two-arm adapter.

    d. Point the syringe nozzle downward and aspirate for 15 seconds, pulling the plunger all the way back, until no bubbles appear in the syringe.

WARNING: If air bubbles appear in the balloon during purging, do not flick the balloon. Orient the balloon in a downward position and reaspirate. Continue purging until bubbles no longer appear. The use of a 20 cc or larger syringe will facilitate purging.

    e. Infuse the contrast mixture into the balloon, inspecting for leaks or air. Repeat aspiration, if necessary, until air bubbles are no longer present in the syringe during aspiration, or in the balloon during inflation.

    f. Release the positive pressure on the syringe plunger and allow the balloon to resume a neutral state pending connection to the inflation device.

g. Remove the 20 cc syringe and attach the inflation device to the balloon leg of the two-arm adapter. Be certain the meniscus of contrast solution is evident at the luer fittings to avoid the possible introduction of air. Finger tighten the connections.

PRELIMINARY TESTING OF THE DILATATION CATHETER

1. Prior to the actual use, the dilatation catheter should be tested by inflating the balloon to the Rated Burst Pressure (see Table 7.1). The time required to fully inflate and deflate the balloon should be checked.

2. Verify that the three-way stopcock connected to the inflation device and dilatation catheter is open. Inflate the balloon to the maximum recommended use pressure (see Table 7.1), and sustain that pressure for five seconds. The balloon should appear fully inflated within ten seconds of pressurization. Retract the plunger to fully deflate the balloon. It should appear fully deflated within ten seconds after applying negative pressure. Repeat the inflations and deflations for three cycles, and record the times. Retract the plunger to fully deflate the balloon, then close the three-way stopcock connected to the inflation device and dilatation catheter. Insert the balloon into the protective sheath, reopen the three-way stopcock and set it aside until ready for use. Do not allow negative pressure to remain on the balloon catheter.

PROCEDURE TECHNIQUE:

1. To insert the catheter:

   a. Prepare and drape the selected entry site.

   b. Administer local anesthetic.

      NOTE: If using the brachial approach, disregard substeps (c) through (i). Perform confirmatory arteriography, including intravenous heparin administration using conventional catheterization techniques. Replace the angiographic catheters with an appropriate Brachial Guiding Catheter using an 0.035 in. or 0.038 in. x 145 cm guide wire. Continue with Step 2.

   c. Cannulate the femoral artery with an appropriate percutaneous needle. Remove the

obturator to confirm that the needle is within the lumen of the artery.

d. Introduce a 0.035 inch or 0.038 inch x 145 cm guide wire, flexible end first, through the needle and into the vessel. Advance the distal tip of the guide wire to the level of the diaphragm under fluoroscopy. Insert a standard angiographic catheter over the guide wire, and advance it to the arch of the aorta.

NOTE: Never advance a guide wire if resistance is encountered without first determining the cause of resistance by fluoroscopy.

e. Anticoagulate the patient with intravenous heparin. Perform baseline coronary arteriography to confirm the severity of the stenosis and to verify that the patient still meets the indication criteria for PTCA.

f. Flush the guiding catheter.

g. Using standard percutaneous techniques, replace the angiographic catheter with a 8 or 9F sheath. Insert the guiding catheter through the sheath over a guide wire. Advance it to the descending aorta under fluoroscopy.

h. Continue advancing the guiding catheter to the ascending aorta under fluoroscopy. The guide wire and introducer should precede the tip of the guiding catheter until its tip is around the aortic arch.

i. Start withdrawing the guide wire as the guiding catheter is advanced into position. Remove the guide wire.

2. Attach a coronary manifold to the side arm of the hemostatic side-arm adapter with a short connecting tubing. Flush the device with normal saline to eliminate any air. To properly flush the valve arm, use a thumb or finger to cap the fitting that connects the arm to the guiding catheter. Open the valve, and flush saline through the device. Close the valve and connect the hemostatic side-arm adapter to the guiding catheter.

3. Join a second hemostatic valve to a coronary manifold with connecting tubing. Flush and fill as in Step 2.

a. Connect the hemostatic valve to the guide wire port of the two-arm adapter of the dilatation catheter. Flush and fill the guide wire lumen of the dilatation catheter with heparinized normal saline.

b. Loosen the knurled knob of the hemostatic valve and open the saline stopcock on the manifold so that fluid drips from the hemostatic valve.

c. Insert a guide wire introducer through the hemostatic valve to facilitate introduction of the guide wire into the dilatation catheter. Advance the guide wire carefully into and through the lumen of the dilatation catheter. Position the tip of the guide wire so that it is just inside the tip of the dilatation catheter.

d. Withdraw the guide wire introducer and tighten the knurled knob so that the valve closes firmly around the guide wire. Close the saline stopcock on the manifold.

4. Aspirate the guiding catheter to free any trapped air. Flush the guiding catheter with normal saline, fill it with contrast medium, and selectively engage it in the appropriate coronary ostium. Confirm the catheter position by arteriography.

5. Remove the balloon sheath.

PRECAUTION: All air must be removed from the FACT™ catheter and displaced with heparinized saline prior to inserting it into the body. Otherwise complications may occur.

6. Loosen the knurled screw fitting on the hemostatic side-arm adapter which is attached to the guiding catheter so that it is possible to pass the dilatation catheter through the valve. Then introduce the dilatation catheter into the guiding catheter. It is imperative that the balloon be fully deflated during this process.

7. Re-tighten the fitting, after the dilatation catheter has been inserted at least 30 to 40 cm into the guiding catheter, to create a seal around the dilatation catheter that does not inhibit movement of the catheter. This will allow continuous recording of proximal coronary artery pressure.

Advance the dilatation catheter and guidewire to the tip of the guiding catheter. Proximal markers located approximately 95 and 105 centimeters from the distal tip aid in identifying how far the dilatation catheter is advanced in brachial and femoral guiding catheters, respectively. When the marker is aligned with the hemostatic valve hub, the dilatation catheter tip has reached the guiding catheter tip (i.e., when using a brachial guiding catheter, use the 95 centimeters marker as a gauge and when using a femoral guiding catheters, use the 105 centimeters marker as a gauge..

PRECAUTION: It is important that the valve be closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon.

Attach the torque device to the guidewire. Keep the valve of the guidewire hemostatic side-arm adapter appropriately closed when the guidewire is in the catheter. When the valve is appropriately closed, intentional movement of the wire is not inhibited.

8. Advance the guidewire, under fluoroscopy, out of the tip of the guiding catheter and select the desired coronary artery. Continue advancing the guidewire to and then across the stenosis while frequently confirming its position with contrast injections through the guiding catheter. The FACT™ catheter may be incrementally advanced following the guidewire to provide additional support to the guidewire as it negotiates the coronary artery and crosses the stenosis. The spring tip of the guidewire may be rotated to facilitate the processes of vessel negotiation and crossing the stenosis by slowly turning the torque device.

9. Hold the guidewire stationary and advance the FACT™ catheter over the guidewire and into the stenosis. The radiopaque balloon marker(s) and a very low pressure (10 to 20 psi) balloon inflation should be used to confirm that the indentation caused by the stenosis is centrally located within the balloon segment before proceeding with the dilatation.

10. Inflate the balloon to perform PTCA per standard procedure. Deflate the balloon. Maintain negative pressure on the balloon between dilatations by pulling negative pressure, then closing the inflation device stopcock.

11. After the first inflation and each subsequent inflation, assess distal coronary blood flow by arteriography through the guiding catheter while the deflated balloon remains in the stenosis. Maintain the guidewire across the stenosis until distal blood flow is adequate. If distal coronary blood flow is reduced and myocardial ischemia develops before an effective dilatation is achieved, the guidewire may be advanced and maintained across the stenosis as the balloon is withdrawn, permitting reperfusion of the distal vessel.

12. Prior to removing the balloon, check the balloon to verify that it is fully deflated and then close the stopcock of the inflation device to maintain the vacuum. With the balloon deflated, simultaneously withdraw the dilatation catheter and guidewire out of the coronary artery and into the lumen of the guiding catheter. Remove the dilatation catheter from the guiding catheter through the hemostatic side-arm adapter. Close the valve of the hemostatic side-arm adapter.

NOTE: The guiding catheter is not recommended for routine arteriography. A standard coronary angiographic catheter should be used for post-angioplasty arteriography.

13. Carefully remove the guiding catheter, then follow standard practice for management of the insertion site.

TABLE I BALLOON COMPLIANCE				
INFLATION PRESSURE (ATMS)	**2.5 mm Balloon Diameter**	**3.0 mm Balloon Diameter**	**3.5 mm Balloon Diameter**	**4.0 mm Balloon Diameter**
2	2.2	2.7	3.2	3.7
3	2.3	2.8	3.3	3.8
4	2.3	2.8	3.3	3.9
5	2.4	2.9	3.4	3.9
6	**2.5**	**3.0**	**3.5**	**4.0**
7	2.6	3.1	3.6	4.1
8	2.7	3.2	3.7	4.2
9	2.8	3.3	3.8	4.3
10	2.9	3.4	3.9	4.4
11	3.0	3.5	4.0	4.5
12	**3.0**	**3.5**	**4.0**	**4.6**
13	3.1	3.6	4.1	4.6
14	3.1	3.6	4.2	4.7
15	3.2	3.7	4.3	4.8
16	3.2	3.7	4.3	4.8

REPACKAGING INSTRUCTIONS:

In the event the catheter must be returned for any reason, return the FACT™ catheter in its original package and shipping box. Contact CardioVascular Dynamics to receive a Return Authorization Number prior to return shipment.

IX. REFERENCES

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by ACC/AHA.

X. WARRANTY AND LIMITATIONS

CardioVascular Dynamics has exercised reasonable care in the manufacture of the FACT™ catheter. CardioVascular Dynamics warrants that the FACT™ catheters shall be free of defects in materials and workmanship upon receipt. CardioVascular Dynamics warranty shall not apply to these products of they have been altered or utilized in a manner not approved by CardioVascular Dynamics or subjected to misuse, negligence or accident. The liabilities of CardioVascular Dynamics arising out of supplying this product whether based on warranty or otherwise, shall in no case exceed the price of this product.

CardioVascular Dynamics makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the re-use of this catheter.

In addition, CardioVascular Dynamics assumes no responsibility or liability for incidental or consequential damages which may result from such re-use.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:

CardioVascular Dynamics, Inc.
13900 Alton Parkway, Suite 122
Irvine, CA 92618
(714) 457-9546 • (800) 721-2284

650-0175

CVD™ ARC Active Response™

Coronary Dilatation Catheter

Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外枠直径最大限	Model Modello Modèle Modelo Modell モデル	Rated Burst Pressure Burstdruck Pression d'eclatement nominale Presión de estallido Pressione massima raccomandata 定格バースト圧
135 cm	**3.5F / 3.0F**	**.014 in**	**6925**	**12 atm**

featuring SlyDx™ *advanced coating technology*

STERILE AND NONPYROGENIC

Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For one procedure only. Do not resterilize. Do not use open or damaged packages. Store in a dry, dark, cool place. Refer to accompanying Instructions for Use.

Steril. Sterilisiert mit Athylenoxid. Pyrogenfrei. Nur zum einmaligen. Gerbrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschadigten. Packungen benutzen. Trocken, dunkel und kuhl aufbewahren. Vor Gebrauch Anleitungen durchlesen.

Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'àbri de la lumiére. Lire la notice avant utilisation.

Estéril. Esterilizado con óxido de etileno. Apirógeno. Para un solo uso. No reesterilizar. No utilizar si el embalaje está abierto o deteriorado. Almacenar en un lugar fresco, uscuro y seco. Leer las instrucciones antes du su uso.

Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

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CAUTION

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U.S. and foreign patents pending

650-0308 Rev. C

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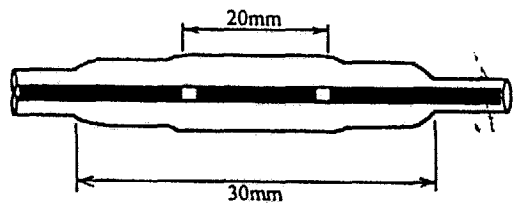
31-30-2870458



CVD™ ARC Active Response™

Balloon Diameter Ballondurchmesser Diamètre du ballon Diámetro del balón Ø del Palloncino 風船の直径	**2.5** mm	Balloon Length Ballonlänge Long du ballon Long del balón Lung del palloncino 風船の長さ	**30** mm	6925 Model

CVD™

ARC Active Response™

Coronary Dilatation Catheter

Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外枠直径最大限	Model Modello Modèle Modelo Modell モデル	Rated Burst Pressure Burstdruck Pression d'eclatement nominale Presión de estallido Pressione massima raccomandata 定格バースト圧
135 cm	**3.5F / 3.0F**	**.014 in**	**6930**	**12 atm**

featuring SlyDx™ *advanced coating technology*

STERILE AND NONPYROGENIC

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Steril. Sterilisiert mit Athylenoxid. Pyrogenfrei. Nur zum einmaligen. Gerbrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschadigten. Packungen benutzen. Trocken, dunkel und kuhl aufbewahren. Vor Gebrauch Anleitungen durchlesen.

Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'àbri de la lumiére. Lire la notice avant utilisation.

Estéril. Esterilizado con óxido de etileno. Apirógeno. Para un solo uso. No reesterilizar. No utilizar si el embalaje está abierto o deteriorado. Almacenar en un lugar fresco, uscuro y seco. Leer las instrucciones antes du su uso.

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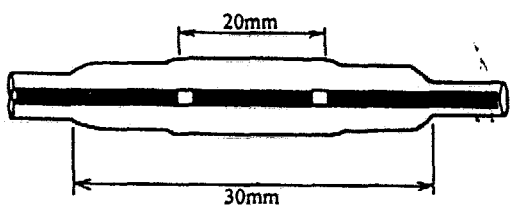

CVD™ ARC Active Response™

Balloon Diameter / Ballondurchmesser / Diamètre du ballon / Diámetro del balòn / Ø del Palloncino / 風船の直径: **3.0** mm

Balloon Length / Ballonlänge / Long du ballon / Long del balón / Lung del palloncino / 風船の長さ: **30** mm

6930 Model

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CVD™ ARC Active Response™

Coronary Dilatation Catheter

Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外枠直径最大限	Model Modello Modèle Modelo Modell モデル	Rated Burst Pressure Burstdruck Pression d'eclatement nominale Presión de estallido Pressione massima raccomandata 定格バースト圧
135 cm	**3.5F / 3.0F**	**.014 in**	**6935**	**12 atm**

featuring SlyDx™ *advanced coating technology*

STERILE AND NONPYROGENIC

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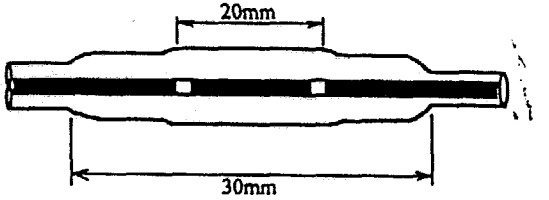

CVD™ ARC Active Response™

Balloon Diameter Ballondurchmesser Diamètre du ballon Diámetro del balón Ø del Palloncino 風船の直径	**3.5** mm	Balloon Length Ballonlänge Long du ballon Long del balón Lung del palloncino 風船の長さ	**30** mm	6935 Model

103

CVD™ ARC Active Response™

Coronary Dilatation Catheter

Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外枠直径最大限	Model Modello Modèle Modelo Modell モデル	Rated Burst Pressure Burstdruck Pression d'eclatement nominale Presión de estallido Pressione massima raccomandata 定格バースト圧
135 cm	**3.5F / 3.0F**	**.014 in**	**6940**	**12 atm**

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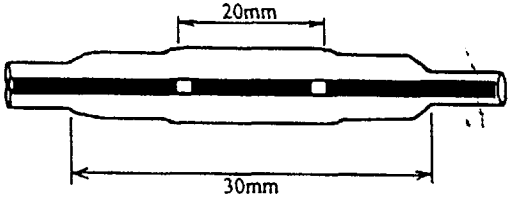

CVD™ ARC Active Response™

Balloon Diameter Ballondurchmesser Diamètre du ballon Diámetro del balón Ø del Palloncino 風船の直径	**4.0** mm	Balloon Length Ballonlänge Long du ballon Long del balón Lung del palloncino 風船の長さ	**30** mm	6940 Model

CORONARY BALLOON DILATATION CATHETER

INSTRUCTION FOR USE

DESCRIPTION

The ARC™ Coronary Balloon Dilatation Catheter is a double-lumen catheter with a balloon near the distal tip. One lumen is used for inflation of the balloon, and the other lumen permits the use of a coronary guide wire to facilitate the advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an expandable segment of known diameter and length at a specific pressure.

The catheter has a 3.5F proximal shaft and 3.0F for the distal shaft segment. Reference markers are located on the proximal catheter shaft 95 cm and 105 cm from the distal tip for the brachial and femoral approaches, respectively.

A two-arm adapter is on the proximal end of the catheter. The sideport of the adapter is connected to the balloon lumen, and has a luer-lock fitting for attaching the catheter to an inflation device. The guide wire port is continuous with the inner lumen of the catheter. The inner lumen allows for free movement of a conventional coronary guide wire equal to or smaller than 0.014 inch.

INDICATIONS

The ARC™ Coronary Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS

- Unprotected left main coronary artery.
- Coronary artery spasm in the absence of a significant stenosis.

WARNINGS

- This device is intended for one time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA. as treatment of this patient population carries special risks.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the Rated Burst Pressure. The Rated Burst Pressure is based on the results of in-vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their Rated Burst Pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.
- Use the catheter prior to the "Use Before" date specified on the package.
- ARC Balloon Dilatation Catheters are not intended for stent expansion.

PRECAUTIONS

- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by physicians trained on the performance of percutaneous transluminal coronary angioplasty.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, the following:

- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- restenosis of the dilated vessel
- hemorrhage or hematoma
- unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- embolism

INSTRUCTIONS FOR USE

MATERIALS REQUIRED FOR PTCA WITH THE ARC™ CORONARY BALLOON DILATATION SYSTEM

Quantity	Item Description*
1	0.035 or 0.038 in. x 145 cm guide wire and introducer catheter
1	0.014 in. or smaller x 175 cm guide wire
1	7 to 9F arterial sheath and dilator set (for the femoral approach only)
2 to 3	Femoral or brachial guiding catheters in appropriate size and configuration for the selected coronary artery.
2	Hemostatic side arm adapters
1	Small vial of 60% contrast medium
1	Inflation device for balloon inflation
1 to 2	ARC™ Coronary Balloon Dilatation Catheter(s). (The dilatation catheter is selected according to the severity of the stenosis and the native vessel size. The inflated diameter of the balloon should approximate the coronary artery diameter, and should never exceed the diameter of the coronary artery proximal and distal to the stenosis. In instances of severe stenosis, a smaller balloon may be needed to begin the dilatation process, and it may then be replaced with a larger balloon to effect a successful dilatation.)

* These materials are single-use items only.

INSPECTION PRIOR TO USE

Prior to angioplasty, all equipment to be used for the procedures, including the dilatation catheter, should be carefully examined to verify proper performance. It is imperative that the balloon of the dilatation catheter be tested to the maximum pressure to be used during the procedure and that its inflation/deflation time be checked.

PREPARATION OF THE DILATATION CATHETER:

To properly prepare the catheter for use, the following steps should be completed:

1. Filling the inflation device.

   a. Prepare the inflation device according to the manufacturer's instructions.

   b. Purge the system of air. Slide the protective sheath off the balloon.

2. Filling the balloon with contrast solution to displace air.

   a. Prepare a mixture of 50/50% contrast media and sterile saline.

   b. Aspirate 4 cc of contrast mixture into a 20 cc or larger syringe.

   c. Attach the syringe to the balloon leg of the two-arm adapter.

   d. Point the syringe nozzle downward and aspirate for 15 seconds, pulling the plunger all the way back, until no bubbles appear in the syringe.

NOTE: If air bubbles appear in the balloon during purging, do not flick the balloon. Orient the balloon in a downward position and reaspirate. Continue purging until bubbles no longer appear. The use of a 20cc or larger syringe will facilitate purging.

   e. Infuse the contrast mixture into the balloon, inspecting for leaks or air. Repeat aspiration, if necessary, until air bubbles are no longer present in the syringe during aspiration, or in the balloon during inflation.

   f. Release the positive pressure on the syringe plunger and allow the balloon to resume a neutral state pending connection to the inflation device.

   g. Remove the 20cc syringe and attach the inflation device to the balloon leg of the two-arm adapter. Be certain the meniscus of contrast solution is evident at the luer fittings to avoid the possible introduction of air. Finger tighten the connections.

PRELIMINARY TESTING OF THE DILATATION CATHETER

1. Prior to the actual use, the dilatation catheter should be tested by inflating the balloon to the Rated Burst Pressure (see Table 1). The time required to fully inflate and deflate the balloon should be checked.

2. Verify that the three-way stopcock connected to the inflation device and dilatation catheter is open. Inflate the balloon to the maximum recommended use pressure (see Table 7.1), and sustain that pressure for five seconds. The balloon should appear fully inflated within ten seconds of pressurization. Retract the plunger to fully deflate the balloon. It should appear fully deflated within ten seconds after applying negative pressure. Repeat the inflations and deflations for three cycles, and record the times. Retract the plunger to fully deflate the balloon, then close the three-way stopcock connected to the inflation device and dilatation catheter. Insert the balloon into the protective sheath, reopen the three-way stopcock and set it aside until ready for use. Do not allow negative pressure to remain on the balloon catheter.

PROCEDURE TECHNIQUE:

1. To insert the catheter:

   a. Prepare and drape the selected entry site.

   b. Administer local anesthetic.

      NOTE: If using the brachial approach, disregard substeps (c) through (i). Perform confirmatory arteriography, including intravenous heparin administration using conventional catheterization techniques. Replace the angiographic catheters with an appropriate Brachial Guiding Catheter using an 0.035 in. or 0.038 in. x 145 cm guide wire. Continue with Step 2.

   c. Cannulate the femoral artery with an appropriate percutaneous needle. Remove the obturator to confirm that the needle is within the lumen of the artery.

   d. Introduce a 0.035 inch or 0.038 inch x 145 cm guide wire, flexible end first, through the needle and into the vessel. Advance the distal tip of the guide wire to the level of the diaphragm under fluoroscopy. Insert a standard angiographic catheter over the guide wire, and advance it to the arch of the aorta.

      NOTE: Never advance a guide wire if resistance is encountered without first determining the cause of resistance by fluoroscopy.

   e. Anticoagulate the patient with intravenous heparin. Perform baseline coronary arteriography to confirm the severity of the stenosis and to verify that the patient still meets the indication criteria for PTCA.

   f. Flush the guiding catheter.

   g. Using standard percutaneous techniques, replace the angiographic catheter with a 8 or 9F sheath. Insert the guiding catheter through the sheath over a guide wire. Advance it to the descending aorta under fluoroscopy.

   h. Continue advancing the guiding catheter to the ascending aorta under fluoroscopy. The guide wire and introducer should precede the tip of the guiding catheter until

i. Start withdrawing the guide wire as the guiding catheter is advanced into position. Remove the guide wire.

2. Attach a coronary manifold to the side arm of the hemostatic side-arm adapter with a short connecting tubing. Flush the device with normal saline to eliminate any air. To properly flush the valve arm, use a thumb or finger to cap the fitting that connects the arm to the guiding catheter. Open the valve, and flush saline through the device. Close the valve and connect the hemostatic side-arm adapter to the guiding catheter.

3. Join a second hemostatic valve to a coronary manifold with connecting tubing. Flush and fill as in Step 2.

   a. Connect the hemostatic valve to the guide wire port of the two-arm adapter of the dilatation catheter. Flush and fill the guide wire lumen of the dilatation catheter with heparinized normal saline.

   b. Loosen the knurled knob of the hemostatic valve and open the saline stopcock on the manifold so that fluid drips from the hemostatic valve.

   c. Insert a guide wire introducer through the hemostatic valve to facilitate introduction of the guide wire into the dilatation catheter. Advance the guide wire carefully into and through the lumen of the dilatation catheter. Position the tip of the guide wire so that it is just inside the tip of the dilatation catheter.

   d. Withdraw the guide wire introducer and tighten the knurled knob so that the valve closes firmly around the guide wire. Close the saline stopcock on the manifold.

4. Aspirate the guiding catheter to free any trapped air. Flush the guiding catheter with normal saline, fill it with contrast medium, and selectively engage it in the appropriate coronary ostium. Confirm the catheter position by arteriography.

5. Remove the balloon sheath.

NOTE: All air must be removed from the ARC™ catheter and displaced with heparinized saline prior to inserting it into the body. Otherwise complications may occur.

6. Loosen the knurled screw fitting on the hemostatic side-arm adapter which is attached to the guiding catheter so that it is possible to pass the dilatation catheter through the valve. Then introduce the dilatation catheter into the guiding catheter. It is imperative that the balloon be fully deflated during this process.

7. Re-tighten the fitting, after the dilatation catheter has been inserted at least 30 to 40 cm into the guiding catheter, to create a seal around the dilatation catheter that does not inhibit movement of the catheter. This will allow continuous recording of proximal coronary artery pressure. Advance the dilatation catheter and guidewire to the tip of the guiding catheter. Proximal markers located approximately 95 and 105 centimeters from the distal tip aid in identifying how far the dilatation catheter is advanced in brachial and femoral guiding catheters, respectively. When the marker is aligned with the hemostatic valve hub, the dilatation catheter tip has reached the guiding catheter tip (i.e., when using a brachial guiding catheter, use the 95 centimeters marker as a gauge and when using a femoral guiding catheters, use the 105 centimeters marker as a gauge).

NOTE: It is important that the valve be closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon.

Attach the torque device to the guidewire. Keep the valve of the guidewire hemostatic side-arm adapter appropriately closed when the guidewire is in the catheter. When the valve is appropriately closed, intentional movement of the wire is not inhibited.

8. Advance the guidewire, under fluoroscopy, out of the tip of the guiding catheter and select the desired coronary artery. Continue advancing the guidewire to and then across the stenosis while frequently confirming its position with contrast injections through the guiding catheter. The ARC™ catheter may be incrementally advanced following the guidewire to provide additional support to the guidewire as it negotiates the coronary artery and crosses the stenosis. The spring tip of the guidewire may be rotated to facilitate the processes of vessel negotiation and crossing the stenosis by slowly turning the torque device.

9. Hold the guidewire stationary and advance the ARC™ catheter over the guidewire and into the stenosis. The radiopaque balloon marker and a very low pressure (10 to 20 psi) balloon inflation should be used to confirm that the indentation caused by the stenosis is centrally located within the balloon segment before proceeding with the dilatation.

10. Inflate the balloon to perform PTCA per standard procedure. Deflate the balloon. Maintain negative pressure on the balloon between dilatations by pulling negative pressure, then closing the inflation device stopcock.

11. After the first inflation and each subsequent inflation, assess distal coronary blood flow by arteriography through the guiding catheter while the deflated balloon remains in the stenosis. Maintain the guidewire across the stenosis until distal blood flow is adequate. If distal coronary blood flow is reduced and myocardial ischemia develops before an effective dilatation is achieved, the guidewire may be advanced and maintained across the stenosis as the balloon is withdrawn, permitting reperfusion of the distal vessel.

12. Prior to removing the balloon, check the balloon to verify that it is fully deflated and then close the stopcock of the inflation device to maintain the vacuum. With the balloon deflated, simultaneously withdraw the dilatation catheter and guidewire out of the coronary artery and into the lumen of the guiding catheter. Remove the dilatation catheter from the guiding catheter through the hemostatic side-arm adapter. Close the valve of the hemostatic side-arm adapter.

NOTE: The guiding catheter is not recommended for routine arteriography. A standard coronary angiographic catheter should be used for post-angioplasty arteriography.

13. Carefully remove the guiding catheter, then follow standard practice for management of the insertion site.

TABLE I BALLOON COMPLIANCE					
INFLATION PRESSURE (ATMS)	**2.5 mm Balloon Diameter**	**3.0 mm Balloon Diameter**	**3.5 mm Balloon Diameter**	**4.0 mm Balloon Diameter**	
2	2.2	2.7	3.2	3.4	
3	2.3	2.8	3.3	3.5	
4	2.3	2.8	3.3	3.6	
5	2.4	2.9	3.4	3.7	
6	2.4	2.9	3.4	3.8	
7	2.5	3.0	3.5	3.9	
8	**2.5**	**3.0**	**3.5**	**4.0**	Nominal Pressure
9	2.6	3.0	3.6	4.1	
10	2.6	3.1	3.7	4.2	
11	2.7	3.2	3.7	4.2	
12	**2.7**	**3.2**	**3.8**	**4.3**	Rated Burst Pressure
13	2.8	3.3	3.8	4.3	
14	2.8	3.3	3.9	4.4	
15	2.8	3.4	3.9	4.4	

REPACKAGING INSTRUCTIONS:

In the event the catheter must be returned for any reason, return the ARC™ catheter in its original package and shipping box. Contact CardioVascular Dynamics to receive a Return Authorization Number prior to return shipment.

REFERENCES

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by ACC/AHA.

WARRANTY AND LIMITATIONS

CardioVascular Dynamics Corporation has exercised reasonable care in the manufacture of the ARC™ catheter. CardioVascular Dynamics warrants that the ARC™ catheters shall be free of defects in materials and workmanship upon receipt. CardioVascular Dynamics warranty shall not apply to these products of they have been altered or utilized in a manner not approved by CardioVascular Dynamics or subjected to misuse, negligence or accident. The liabilities of CardioVascular Dynamics arising out of supplying this product whether based on warranty or otherwise, shall in no case exceed the price of this product.

CardioVascular Dynamics makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the re-use of this catheter.

In addition, CardioVascular Dynamics assumes no responsibility or liability for incidental or consequential damages which may result from such re-use.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:

CVD
CardioVascular Dynamics, Inc.
13900 Alton Parkway, Suite 122
Irvine, CA 92618
(714) 457-9546 • (800) 721-2284

ARC Balloon Compliancy Chart (2 sided)

ARC
Active Response™

Inflation Pressure (ATMs)	2.5 mm Center Diameter	3.0 mm Center Diameter	3.5 mm Center Diameter	4.0 mm Center Diameter	
2	2.2	2.7	3.2	3.4	
3	2.3	2.8	3.3	3.5	
4	2.3	2.8	3.3	3.6	
5	2.4	2.9	3.4	3.7	
6	2.4	2.9	3.4	3.8	
7	2.5	3.0	3.5	3.9	
8*	2.5 2.5 2.5	3.0 3.0 3.0	3.5 3.5 3.5	4.0 4.0 4.0	Nominal
9	2.6	3.0	3.6	4.1	
10	2.6	3.1	3.7	4.2	
11	2.7	3.2	3.7	4.2	
12	2.7	3.2	3.8	4.3	Rated Burst Pressure
13	2.8	3.3	3.8	4.3	
14	2.8	3.3	3.9	4.4	
15	2.8	3.4	3.9	4.4	

**Indicates Proximal/Distal Section Measurements*

Bolded text represents pressures above the rated burst pressure. Do not exceed rated burst.

650-0212 Rev. B

CVD
CardioVascular Dynamics, Inc.


Dr. Maurice Buchbinder
Signature Series
CMD

C♡D™ LYNX™ CORONARY DILATATION CATHETER

DRAFT LABELING

STERILE AND NONPYROGENIC

Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For one procedure only. Do not resterilize. Do not use open or damaged packages. Store in a dry, dark, cool place. Refer to accompanying Instructions for Use.

Steril. Sterilisiert mit Athylenoxid. Pyrogenfrei. Nur zum einmaligen. Gerbrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschadigten. Packungen benutzen. Trocken, dunkel und kuhl aufbewahren. Vor Gebrauch Anleitungen durchlesen.

Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'àbri de la lumiére. Lire la notice avant utilisation.

Estéril. Esterilizado con óxido de etileno. Apirógeno. Para un solo uso. No reesterilizar. No utilizar si el embalaje está abierto o deteriorado. Almacenar en un lugar fresco, uscuro y seco. Leer las instrucciones antes de usar.

Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

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CAUTION

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CONTENTS

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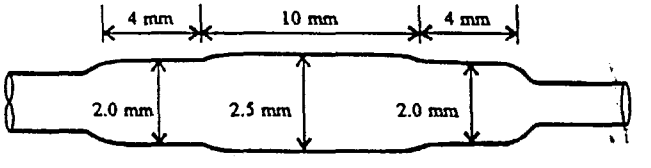
Shaft Length Schaftlänge Longueur du corps Longitud del cuerpo Lunghezza dello stelo シャフトの長さ	Shaft Diameter Schaftdurchmesser Diamètre du corps Diámetro del cuerpo Diametro dello stelo シャフトの直径	Max. Guide Wire O.D. Max. F.-Drahtdurchmesser D.E. max du guide D.E. máx de la guia D.E. max. della guida 誘導線の外枠直径最大限
135 cm	**3.3F / 2.6F**	**.014 in**

featuring SlyDx™ *advanced coating technology*

C♡D™ CARDIOVASCULAR DYNAMICS, INC.
13900 Alton Parkway, Suite 122
Irvine, California 92618
714-457-9546 • FAX 714-457-9561
Customer Service 800-721-2284



Nominal at 12 Atmospheres

650-0191 Rev. 1

Manufactured under one or more of the following patents:
5,295,962; 5,344,402; 5,368,566; 5,421,826; 5,470,313; 5,522,800
U.S. and foreign patents pending

C♡D™ LYNX™

16 atm Rated Burst

Balloon Diameter / Ballondurchmesser / Diamètre du ballon / Diámetro del balón / Ø del Palloncino / 風船の直径
2.0 **2.5** mm

Balloon Length / Ballonlänge / Long du ballon / Long del balón / Lung del palloncino / 風船の長さ
18 mm

3025 Model

690

CVD™ LYNX™ CORONARY DILATATION CATHETER

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Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'àbri de la lumiére. Lire la notice avant utilisation.

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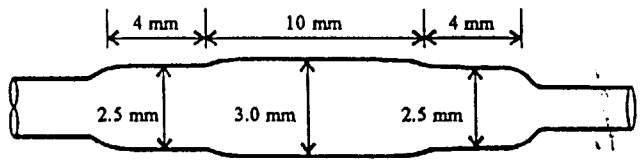

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U.S. and foreign patents pending

CVD™ LYNX™

16 atm Rated Burst

Balloon Diameter / Ballondurchmesser / Diamètre du ballon / Diámetro del balón / Ø del Palloncino / 風船の直径: **2.5** **3.0** mm

Balloon Length / Ballonlänge / Long du ballon / Long del balón / Lung del palloncino / 風船の長さ: **18** mm

3030 Model

DRAFT LABELING

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Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

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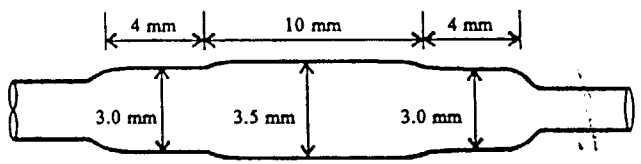

Nominal at 12 Atmospheres

650-0193 Rev. 1

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CVD™ LYNX™

16 atm Rated Burst

Balloon Diameter / Ballondurchmesser / Diamètre du ballon / Diámetro del balón / Ø del Palloncino / 風船の直径: **3.0** **3.5** mm

Balloon Length / Ballonlänge / Long du ballon / Long del balón / Lung del palloncino / 風船の長さ: **18** mm

3035 Model

071

C♡D™ LYNX™ CORONARY DILATATION CATHETER

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Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

殺菌 エチレン酸化ガスで殺菌。不加熱。一手段のみ。再殺菌をしないでください。開封または破れたパッケージは使用しないでください。乾燥した冷暗所に保存してください。使用につきましては、説明書を参考にしてください。

CAUTION

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135 cm	**3.3F / 2.6F**	**.014 in**

featuring SlyDx™ *advanced coating technology*

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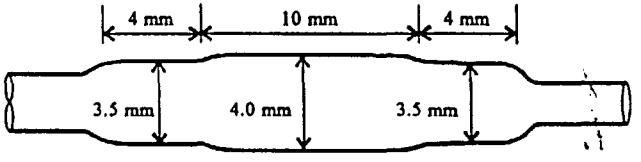

Nominal at 12 Atmospheres

650-0194 Rev. 1

Manufactured under one or more of the following patents:
5,295,962; 5,344,402; 5,368,566; 5,421,826; 5,470,313; 5,522,800
U.S. and foreign patents pending

C♡D™ LYNX™

16 atm Rated Burst

Balloon Diameter / Ballondurchmesser / Diamètre du ballon / Diámetro del balón / Ø del Palloncino / 風船の直径: **3.5** | **4.0** mm

Balloon Length / Ballonlänge / Long du ballon / Long del balón / Lung del palloncino / 風船の長さ: **18** mm

3040 Model

C♡D™ LYNX™ CORONARY DILATATION CATHETER

STERILE AND NONPYROGENIC

Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For one procedure only. Do not resterilize. Do not use open or damaged packages. Store in a dry, dark, cool place. Refer to accompanying Instructions for Use.

Steril. Sterilisiert mit Athylenoxid. Pyrogenfrei. Nur zum einmaligen. Gerbrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschadigten. Packungen benutzen. Trocken, dunkel und kuhl aufbewahren. Vor Gebrauch Anleitungen durchlesen.

Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'ábri de la lumiére. Lire la notice avant utilisation.

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Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

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135 cm	**3.3F / 2.6F**	**.014 in**

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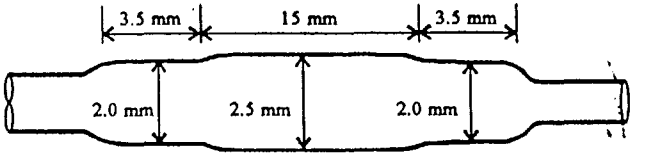

Nominal at 12 Atmospheres

650-0267 Rev. 1

Manufactured under one or more of the following patents:
5,295,962; 5,344,402; 5,368,566; 5,421,826; 5,470,313; 5,522,800
U.S. and foreign patents pending

C♡D™ LYNX™

16 atm Rated Burst

Balloon Diameter / Ballondurchmesser / Diamètre du ballon / Diámetro del balón / Ø del Palloncino / 風船の直径: **2.0** **2.5** mm

Balloon Length / Ballonlänge / Long du ballon / Long del balón / Lung del palloncino / 風船の長さ: **22** mm

3125 Model

DRAFT LABELING

C♡D™ LYNX™ CORONARY DILATATION CATHETER

DRAFT LABELING

STERILE AND NONPYROGENIC

Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For one procedure only. Do not resterilize. Do not use open or damaged packages. Store in a dry, dark, cool place. Refer to accompanying Instructions for Use.

Steril. Sterilisiert mit Athylenoxid. Pyrogenfrei. Nur zum einmaligen. Gerbrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschadigten. Packungen benutzen. Trocken, dunkel und kuhl aufbewahren. Vor Gebrauch Anleitungen durchlesen.

Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'àbri de la lumiére. Lire la notice avant utilisation.

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Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

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135 cm	**3.3F / 2.6F**	**.014 in**

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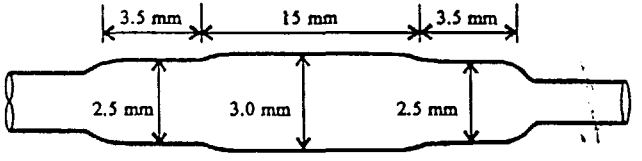

Nominal at 12 Atmospheres

650-0268 Rev. 1

Manufactured under one or more of the following patents:
5,295,962; 5,344,402; 5,368,566; 5,421,826; 5,470,313; 5,522,800
U.S. and foreign patents pending

C♡D™ LYNX™

16 atm Rated Burst

Balloon Diameter / Ballondurchmesser / Diamètre du ballon / Diámetro del balón / Ø del Palloncino / 風船の直径: **2.5** **3.0** mm

Balloon Length / Ballonlänge / Long du ballon / Long del balón / Lung del palloncino / 風船の長さ: **22** mm

3130 Model

C♡D™ LYNX™ CORONARY DILATATION CATHETER

STERILE AND NONPYROGENIC

Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For one procedure only. Do not resterilize. Do not use open or damaged packages. Store in a dry, dark, cool place. Refer to accompanying Instructions for Use.

Steril. Sterilisiert mit Athylenoxid. Pyrogenfrei. Nur zum einmaligen. Gerbrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschadigten. Packungen benutzen. Trocken, dunkel und kuhl aufbewahren. Vor Gebrauch Anleitungen durchlesen.

Stérile. Stérilisé à l'oxyde d'éthyléne. Apyrogéne. A usage unique. Ne pas restériliser. Vérifier l'intégrité du protecteur individuel de stérilité avant usage. Détruire l'objet aprés usage. A conserver dans un endroit frais et sec, a l'àbri de la lumiére. Lire la notice avant utilisation.

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Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

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Longueur du corps	Diamètre du corps	D.E. max du guide
Longitud del cuerpo	Diámetro del cuerpo	D.E. máx de la guia
Lunghezza dello stelo	Diametro dello stelo	D.E. max. della guida
シャフトの長さ	シャフトの直径	誘導線の外枠直径最大限
135 cm	**3.3F / 2.6F**	**.014 in**

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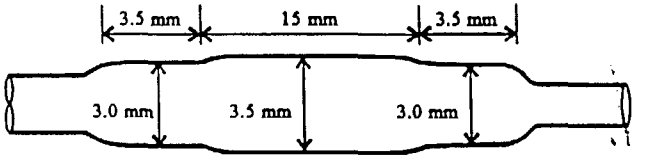

Nominal at 12 Atmospheres

650-0269 Rev. 1

Manufactured under one or more of the following patents:
5,295,962; 5,344,402; 5,368,566; 5,421,826; 5,470,313; 5,522,800
U.S. and foreign patents pending

C♡D™ LYNX™

16 atm Rated Burst

Balloon Diameter / Ballondurchmesser / Diamètre du ballon / Diámetro del balón / Ø del Palloncino / 風船の直径: **3.0** **3.5** mm

Balloon Length / Ballonlänge / Long du ballon / Long del balón / Lung del palloncino / 風船の長さ: **22** mm

3135 Model

DRAFT LABELING

CardioVascular Dynamics, Inc. LYNX™ Coronary Balloon Dilatation Catheter
PMA Supplement August 23, 1996

Section VII: Labeling
Page 8

075

DRAFT LABELING

CVD™ LYNX™ CORONARY DILATATION CATHETER

STERILE AND NONPYROGENIC

Sterile. Sterilized with ethylene oxide gas. Nonpyrogenic. For one procedure only. Do not resterilize. Do not use open or damaged packages. Store in a dry, dark, cool place. Refer to accompanying Instructions for Use.

Steril. Sterilisiert mit Athylenoxid. Pyrogenfrei. Nur zum einmaligen. Gerbrauch bestimmt. Nicht resterilisieren. Keine offenen oder beschadigten. Packungen benutzen. Trocken, dunkel und kuhl aufbewahren. Vor Gebrauch Anleitungen durchlesen.

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Estéril. Esterilizado con óxido de etileno. Apirógeno. Para un solo uso. No reesterilizar. No utilizar si el embalaje está abierto o deteriorado. Almacenar en un lugar fresco, oscuro y seco. Leer las instrucciones antes de usar.

Sterile. Sterilizzato ad ossido di etilene Apirogeno. Monouso. Non risterilizzare. No usare confezioni aperte o danneggiate. Conservare in luogo fresco ed asciutto ed al riparo dalla luce. Leggere attentamente le istruzioni.

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135 cm	**3.3F / 2.6F**	**.014 in**

featuring SlyDx™ *advanced coating technology*

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Irvine, California 92618
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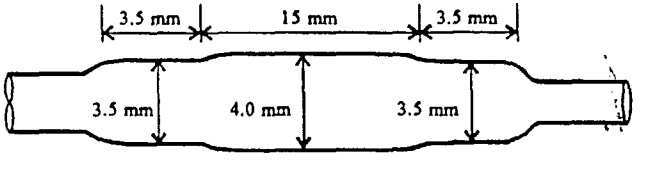

Nominal at 12 Atmospheres

650-0270 Rev. 1

CVD™ LYNX™

16 atm Rated Burst

Balloon Diameter / Ballondurchmesser / Diamètre du ballon / Diámetro del balón / Ø del Palloncino / 風船の直径: **3.5** | **4.0** mm

Balloon Length / Ballonlänge / Long du ballon / Long del balón / Lung del palloncino / 風船の長さ: **22** mm

3140 Model

LABEL, EXPIRATION DATE

Expires:
Lot No.

SECTION VII.B. DRAFT PACKAGE INSERT

I. DEVICE NAME: LYNX™ CORONARY BALLOON DILATATION CATHETER

II. DESCRIPTION

The LYNX™ Coronary Balloon Dilatation Catheter is a double-lumen catheter with a balloon near the distal tip. One lumen is used for inflation of the balloon, and the other lumen permits the use of a coronary guide wire to facilitate the advancement of the catheter to and through the stenosis to be dilated. The balloon is designed to provide an expandable segment of known diameter and length at a specific pressure.

The LYNX™ balloon is formed in a stepped manner so that for the working length of the 18 mm balloon, the center section (10 mm) is formed to the nominal diameter (i.e. 3.5 mm) and the proximal and distal ends of the balloon is stepped down by 0.5 mm (i.e. 3.0 mm).

The nominal diameter of the balloon at 12 atmospheres refers to the center section of the balloon; 10 mm for the 18 mm balloon and a 15 mm center section for the 22 mm balloon.

The catheter is available with a 2.0/2.5 mm balloon, a 2.5/3.0 mm balloon, a 3.0/3.5 mm balloon or a 3.5/4.0 mm balloon. The catheter has a 3.3F proximal shaft and 2.6F for the distal shaft segment. Reference markers are located on the proximal catheter shaft 95 cm and 105 cm from the distal tip for the brachial and femoral approaches, respectively. There are also 2 radiopaque markers at the center section of the balloon.

A two-arm adapter is on the proximal end of the catheter. The sideport of the adapter is connected to the balloon lumen, and has a luer-lock fitting for attaching the catheter to an inflation device. The guide wire port is continuous with the inner lumen of the catheter. The inner lumen allows for free movement of a conventional coronary guide wire equal to or smaller than 0.014 inch.

III. INDICATIONS

The LYNX™ Coronary Balloon Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.

IV. CONTRAINDICATIONS

- Unprotected left main coronary artery.
- Coronary artery spasm in the absence of a significant stenosis.

V. WARNINGS

- This device is intended for one time use only. Do NOT resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.
- To reduce the potential for vessel damage the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.
- PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration, including possible hemodynamic support during PTCA. as treatment of this patient population carries special risks.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.
- Balloon pressure should not exceed the Rated Burst Pressure. The Rated Burst Pressure is based on the results of in-vitro testing. At least 99.9 percent of the balloons, (with a 95 percent confidence) will not burst at or below their Rated Burst Pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.
- Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

- Use the catheter prior to the "Use Before" date specified on the package.
- LYNX™ Balloon Dilatation catheters are not intended for stent expansion.

VI. PRECAUTIONS

- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- The catheter system should be used only by physicians trained on the performance of percutaneous transluminal coronary angioplasty.
- During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.
- Carefully review the balloon compliancy data in Table I. Please note balloon diameter versus pressure. The balloon is nominal at 12 atmospheres.

VII. ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, the following:

- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- restenosis of the dilated vessel
- hemorrhage or hematoma
- unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- embolism

VIII. INSTRUCTIONS FOR USE

MATERIALS REQUIRED FOR PTCA WITH THE LYNX™ CORONARY BALLOON DILATATION SYSTEM

Quantity	Item Description*
1	0.035 or 0.038 in. x 145 cm guide wire and introducer catheter
1	0.014 in. or smaller x 175 cm guide wire
1	7 to 9F arterial sheath and dilator set (for the femoral approach only)
2 to 3	Femoral or brachial guiding catheters in appropriate size and configuration for the selected coronary artery.
2	Hemostatic side arm adapters
1	Small vial of 60% contrast medium
1	Inflation device for balloon inflation
1 to 2	LYNX™ Coronary Balloon Dilatation Catheter(s). The dilatation catheter is selected according to the severity of the stenosis and the native vessel size. The inflated diameter of the balloon should approximate the coronary artery diameter, and should never exceed the diameter of the coronary artery proximal and distal to the stenosis. In instances of severe stenosis, a smaller balloon may be needed to begin the dilatation process, and it may then be replaced with a larger balloon to effect a successful dilatation.

* These materials are single-use items only.

INSPECTION PRIOR TO USE

Prior to angioplasty, all equipment to be used for the procedures, including the dilatation catheter, should be carefully examined to verify proper performance. It is imperative that the balloon of the dilatation catheter be tested to the maximum pressure to be used during the procedure and that its inflation/deflation time be checked.

PREPARATION OF THE DILATATION CATHETER:

To properly prepare the catheter for use, the following steps should be completed:

1. Filling the inflation device.

   a. Prepare the inflation device according to the manufacturer's instructions.

   b. Purge the system of air. Slide the protective sheath off the balloon.

2. Filling the balloon with contrast solution to displace air.

   a. Prepare a mixture of 50/50% contrast media and sterile saline.

   b. Aspirate 4 cc of contrast mixture into a 20 cc or larger syringe.

   c. Attach the syringe to the balloon leg of the two-arm adapter.

   d. Point the syringe nozzle downward and aspirate for 15 seconds, pulling the plunger all the way back, until no bubbles appear in the syringe.

NOTE: If air bubbles appear in the balloon during purging, do not flick the balloon. Orient the balloon in a downward position and reaspirate. Continue purging until bubbles no longer appear. The use of a 20 cc or larger syringe will facilitate purging.

   e. Infuse the contrast mixture into the balloon, inspecting for leaks or air. Repeat aspiration, if necessary, until air bubbles are no longer present in the syringe during aspiration, or in the balloon during inflation.

   f. Release the positive pressure on the syringe plunger and allow the balloon to resume a neutral state pending connection to the inflation device.

g. Remove the 20 cc syringe and attach the inflation device to the balloon leg of the two-arm adapter. Be certain the meniscus of contrast solution is evident at the luer fittings to avoid the possible introduction of air. Finger tighten the connections.

PRELIMINARY TESTING OF THE DILATATION CATHETER

1. Prior to the actual use, the dilatation catheter should be tested by inflating the balloon to the Rated Burst Pressure (see Table 7.1). The time required to fully inflate and deflate the balloon should be checked.

2. Verify that the three-way stopcock connected to the inflation device and dilatation catheter is open. Inflate the balloon to the nominal inflation pressure (see Table 7.1), and sustain that pressure for five seconds. The balloon should appear fully inflated within ten seconds of pressurization. Retract the plunger to fully deflate the balloon. It should appear fully deflated within twenty-five seconds after applying negative pressure. Repeat the inflations and deflations for three cycles, and record the times. Retract the plunger to fully deflate the balloon, then close the three-way stopcock connected to the inflation device and dilatation catheter. Insert the balloon into the protective sheath, reopen the three-way stopcock and set it aside until ready for use. Do not allow negative pressure to remain on the balloon catheter.

PROCEDURE TECHNIQUE:

1. To insert the catheter:

   a. Prepare and drape the selected entry site.

   b. Administer local anesthetic.

      NOTE: If using the brachial approach, disregard substeps (c) through (i). Perform confirmatory arteriography, including intravenous heparin administration using conventional catheterization techniques. Replace the angiographic catheters with an appropriate Brachial Guiding Catheter using an 0.035 in. or 0.038 in. x 145 cm guide wire. Continue with Step 2.

   c. Cannulate the femoral artery with an appropriate percutaneous needle. Remove the

obturator to confirm that the needle is within the lumen of the artery.

d. Introduce a 0.035 inch or 0.038 inch x 145 cm guide wire, flexible end first, through the needle and into the vessel. Advance the distal tip of the guide wire to the level of the diaphragm under fluoroscopy. Insert a standard angiographic catheter over the guide wire, and advance it to the arch of the aorta.

NOTE: Never advance a guide wire if resistance is encountered without first determining the cause of resistance by fluoroscopy.

e. Anticoagulate the patient with intravenous heparin. Perform baseline coronary arteriography to confirm the severity of the stenosis and to verify that the patient still meets the indication criteria for PTCA.

f. Flush the guiding catheter.

g. Using standard percutaneous techniques, replace the angiographic catheter with a 7F to 9F sheath. Insert the guiding catheter through the sheath over a guide wire. Advance it to the descending aorta under fluoroscopy.

h. Continue advancing the guiding catheter to the ascending aorta under fluoroscopy. The guide wire and introducer should precede the tip of the guiding catheter until its tip is around the aortic arch.

i. Start withdrawing the guide wire as the guiding catheter is advanced into position. Remove the guide wire.

2. Attach a coronary manifold to the side arm of the hemostatic side-arm adapter with a short connecting tubing. Flush the device with normal saline to eliminate any air. To properly flush the valve arm, use a thumb or finger to cap the fitting that connects the arm to the guiding catheter. Open the valve, and flush saline through the device. Close the valve and connect the hemostatic side-arm adapter to the guiding catheter.

3. Join a second hemostatic valve to a coronary manifold with connecting tubing. Flush and fill as in Step 2.

   a. Connect the hemostatic valve to the guide wire port of the two-arm adapter of the dilatation catheter. Flush and fill the guide wire lumen of the dilatation catheter with heparinized normal saline.

   b. Loosen the knurled knob of the hemostatic valve and open the saline stopcock on the manifold so that fluid drips from the hemostatic valve.

   c. Insert a guide wire introducer through the hemostatic valve to facilitate introduction of the guide wire into the dilatation catheter. Advance the guide wire carefully into and through the lumen of the dilatation catheter. Position the tip of the guide wire so that it is just inside the tip of the dilatation catheter.

   d. Withdraw the guide wire introducer and tighten the knurled knob so that the valve closes firmly around the guide wire. Close the saline stopcock on the manifold.

4. Aspirate the guiding catheter to free any trapped air. Flush the guiding catheter with normal saline, fill it with contrast medium, and selectively engage it in the appropriate coronary ostium. Confirm the catheter position by arteriography.

5. Remove the balloon sheath.

NOTE: All air must be removed from the LYNX™ catheter and displaced with heparinized saline prior to inserting it into the body. Otherwise complications may occur.

6. Loosen the knurled screw fitting on the hemostatic side-arm adapter which is attached to the guiding catheter so that it is possible to pass the dilatation catheter through the valve. Then introduce the dilatation catheter into the guiding catheter. It is imperative that the balloon be fully deflated during this process.

7. Re-tighten the fitting, after the dilatation catheter has been inserted at least 30 to 40 cm into the guiding catheter, to create a seal around the

dilatation catheter that does not inhibit movement of the catheter. This will allow continuous recording of proximal coronary artery pressure. Advance the dilatation catheter and guidewire to the tip of the guiding catheter. Proximal markers located approximately 95 and 105 centimeters from the distal tip aid in identifying how far the dilatation catheter is advanced in brachial and femoral guiding catheters, respectively. When the marker is aligned with the hemostatic valve hub, the dilatation catheter tip has reached the guiding catheter tip (i.e., when using a brachial guiding catheter, use the 95 centimeters marker as a gauge and when using a femoral guiding catheters, use the 105 centimeters marker as a gauge).

NOTE: It is important that the valve be closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon.

Attach the torque device to the guidewire. Keep the valve of the guidewire hemostatic side-arm adapter appropriately closed when the guidewire is in the catheter. When the valve is appropriately closed, intentional movement of the wire is not inhibited.

8. Advance the guidewire, under fluoroscopy, out of the tip of the guiding catheter and select the desired coronary artery. Continue advancing the guidewire to and then across the stenosis while frequently confirming its position with contrast injections through the guiding catheter. The LYNX™ catheter may be incrementally advanced following the guidewire to provide additional support to the guidewire as it negotiates the coronary artery and crosses the stenosis. The spring tip of the guidewire may be rotated to facilitate the processes of vessel negotiation and crossing the stenosis by slowly turning the torque device.

9. Hold the guidewire stationary and advance the LYNX™ catheter over the guidewire and into the stenosis. The radiopaque balloon markers and a very low pressure (10 to 20 psi) balloon inflation should be used to confirm that the indentation caused by the stenosis is centrally located within the balloon segment before proceeding with the dilatation.

10. Inflate the balloon to perform PTCA per standard procedure. Deflate the balloon. Maintain negative

pressure on the balloon between dilatations by pulling negative pressure, then closing the inflation device stopcock.

11. After the first inflation and each subsequent inflation, assess distal coronary blood flow by arteriography through the guiding catheter while the deflated balloon remains in the stenosis. Maintain the guidewire across the stenosis until distal blood flow is adequate. If distal coronary blood flow is reduced and myocardial ischemia develops before an effective dilatation is achieved, the guidewire may be advanced and maintained across the stenosis as the balloon is withdrawn, permitting reperfusion of the distal vessel.

12. Prior to removing the balloon, check the balloon to verify that it is fully deflated and then close the stopcock of the inflation device to maintain the vacuum. With the balloon deflated, simultaneously withdraw the dilatation catheter and guidewire out of the coronary artery and into the lumen of the guiding catheter. Remove the dilatation catheter from the guiding catheter through the hemostatic side-arm adapter. Close the valve of the hemostatic side-arm adapter.

NOTE: The guiding catheter is not recommended for routine arteriography. A standard coronary angiographic catheter should be used for post-angioplasty arteriography.

13. Carefully remove the guiding catheter, then follow standard practice for management of the insertion site.

TABLE 7.1

BALLOON COMPLIANCE

INFLATION PRESSURE (ATMS)	2.0/2.5 mm Balloon Diameter			2.5/3.0 mm Balloon Diameter			3.0/3.5 mm Balloon Diameter			3.5/4.0 mm Balloon Diameter			
	Prox	Center	Distal	Prox	Center	Distal	Prox	Center	Distal	Prox	Center	Distal	
2	1.9	2.4	1.9	2.4	2.9	2.4	2.8	3.4	2.8	3.3	3.8	3.3	
3	1.9	2.4	1.9	2.4	2.9	2.4	2.8	3.4	2.8	3.4	3.8	3.4	
4	1.9	2.4	1.9	2.4	2.9	2.4	2.9	3.4	2.9	3.4	3.9	3.4	
5	2.0	2.4	2.0	2.4	2.9	2.4	2.9	3.5	2.9	3.4	3.9	3.4	
6	2.0	2.4	2.0	2.4	3.0	2.4	2.9	3.5	2.9	3.4	3.9	3.4	
7	2.0	2.4	2.0	2.4	3.0	2.4	2.9	3.5	2.9	3.4	3.9	3.4	
8	2.0	2.5	2.0	2.5	3.0	2.5	2.9	3.5	2.9	3.4	3.9	3.4	
9	2.0	2.5	2.0	2.5	3.0	2.5	2.9	3.5	2.9	3.5	3.9	3.5	
10	2.0	2.5	2.0	2.5	3.0	2.5	3.0	3.5	3.0	3.5	3.9	3.5	
11	2.0	2.5	2.0	2.5	3.0	2.5	3.0	3.5	3.0	3.5	4.0	3.5	
12	**2.0**	**2.5**	**2.0**	**2.5**	**3.0**	**2.5**	**3.0**	**3.5**	**3.0**	**3.5**	**4.0**	**3.5**	**Nominal Inflation Pressure**
13	2.0	2.5	2.0	2.5	3.0	2.5	3.0	3.5	3.0	3.5	4.0	3.5	
14	2.0	2.5	2.0	2.6	3.1	2.6	3.0	3.6	3.0	3.5	4.0	3.5	
15	2.1	2.5	2.1	2.6	3.1	2.6	3.0	3.6	3.0	3.5	4.0	3.5	
16	**2.1**	**2.5**	**2.1**	**2.6**	**3.1**	**2.6**	**3.0**	**3.6**	**3.0**	**3.6**	**4.0**	**3.6**	**Rated Burst Pressure**
17	2.1	2.5	2.1	2.6	3.1	2.6	3.1	3.6	3.1	3.6	4.1	3.6	
18	2.1	2.5	2.1	2.6	3.2	2.6	3.1	3.6	3.1	3.6	4.1	3.6	
19	2.1	2.5	2.1	2.6	3.2	2.6	3.2	3.6	3.2	3.6	4.2	3.6	
20	2.1	2.5	2.1	2.7	3.2	2.7	3.2	3.7	3.2	3.7	4.2	3.7	

REPACKAGING INSTRUCTIONS:

In the event the catheter must be returned for any reason, return the LYNX™ catheter in its original package and shipping box. Contact CardioVascular Dynamics to receive a Return Authorization Number prior to return shipment.

IX. REFERENCES

The physician should consult recent literature on current medical practice on balloon dilatation, such as that published by ACC/AHA.

X. WARRANTY AND LIMITATIONS

CardioVascular Dynamics has exercised reasonable care in the manufacture of the LYNX™ catheter. CardioVascular Dynamics warrants that the LYNX™ catheters shall be free of defects in materials and workmanship upon receipt. CardioVascular Dynamics warranty shall not apply to these products of they have been altered or utilized in a manner not approved by CardioVascular Dynamics or subjected to misuse, negligence or accident. The liabilities of CardioVascular Dynamics arising out of supplying this product whether based on warranty or otherwise, shall in no case exceed the price of this product.

CardioVascular Dynamics makes no warranty, representation or condition of any kind, whether expressed or implied (including any warranty of merchantability, suitability or fitness for a particular purpose) respecting the re-use of this catheter.

In addition, CardioVascular Dynamics assumes no responsibility or liability for incidental or consequential damages which may result from such re-use.

ADDITIONAL QUESTIONS REGARDING THIS PRODUCT SHOULD BE DIRECTED TO:

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